

**AGGRESSIVE E-CIGARETTE MARKETING AND  
POTENTIAL CONSEQUENCES FOR YOUTH**

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**HEARING**

BEFORE THE

COMMITTEE ON COMMERCE,  
SCIENCE, AND TRANSPORTATION  
UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

—————  
JUNE 18, 2014  
—————

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

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## **AGGRESSIVE E-CIGARETTE MARKETING AND POTENTIAL CONSEQUENCES FOR YOUTH**

**WEDNESDAY, JUNE 18, 2014**

U.S. SENATE,  
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,  
*Washington, DC.*

The Committee met, pursuant to notice, at 2:34 p.m. in room SR-253, Russell Senate Office Building, Hon. John D. Rockefeller IV, Chairman of the Committee, presiding.

### **OPENING STATEMENT OF HON. JOHN D. ROCKEFELLER IV, U.S. SENATOR FROM WEST VIRGINIA**

The CHAIRMAN. Well, I'm just going to go ahead.

John Thune is worth waiting for under all circumstances, but we got a lot of people who may just want to get going.

Okay. Today the Committee is examining the marketing of e-cigarettes, and I should warn you that, emotionally, I'm on edge on this whole subject, I'm on edge—a product whose popularity has recently been soaring including and, especially, among young people. We will hear today, I assume, from the tobacco companies, or whatever they call themselves, that they're just marketing to adults, which I'm going to find an amazing answer. And we will probe that.

E-cigarettes are battery-operated products that vaporize a liquid containing something called nicotine. And we all remember that; don't we? Eight people with their hands raised. Now we know that a cigarette and an e-cigarette are somewhat different. But, nicotine is nicotine. Little kids are little kids. And they're looking for things. And they're looking for things which they get to see a lot of it in advertising. One of the nice things is that you can sort of mimic the act of smoking. It's cool. Kids are cool.

These products are relatively new and their long-term health effects are unknown at this point, which, to me, raises the question why in heaven's name are they going ahead and marketing these things and selling these things and putting them online with the results of health studies, which are being done seriously, are still out?

Why would you do that? You want to make money. That's your answer. You would—that's your answer. You'll tell me you're just talking to adults, but you're not. You want to make money. So you plunge in, get what you can, and then the studies come out. Then, you go ahead and do it until the FDA puts some nice rules and regulations on you.

These products are relatively new and their long-term health effects are unknown; however, they do indicate, they do deliver the nicotine and it's a highly addictive substance. Nicotine does a variety of things but it can effect brain development among young kids.

Some people claim that e-cigarettes can help adults quit smoking combustible cigarettes while others are concerned they may reduce quitting by encouraging dual use of e-cigarettes with combustible cigarettes. But we have not done enough research yet and I admit that, to resolve this question. But that is not the focus of this hearing. Instead, we're going to focus on how marketing of erates, excuse me, I like erates a lot—e-cigarettes reaches America's youth and what consequences that that fact may have.

Since generations of cigarette users became addicted to nicotine in their youth, it only makes sense to be concerned about whether e-cigarettes could get also young people on a similar path to addiction. Addiction, under any form, I think is a bad thing. And, I don't know, we figured maybe about 4,000 kids in West Virginia are affected by this badly.

The last thing anyone should want to do is to encourage young people to start using a new nicotine delivery product. It's the last thing. Researchers, they're not sure what the long-term health consequences, not sure about the short-term health consequences, ah, but there's an opening in the market. So boom, let's get it in and make as much as we can because there are no regulations. That's our fault. I apologize for that.

And welcome the distinguished Senator.

If you put West Virginia and South Dakota together, you have approximately 72 percent of the United States territory.

[Laughter.]

Senator THUNE. It seems that way.

The CHAIRMAN. Health experts are sounding several alarms on these virtually unregulated products. In addition to the issue of nicotine addiction, e-cigarette that are related cause calls to poison control centers to be very much on the rise and particularly involving children, and particularly involving children under the age of five. Yes, five.

Moreover, some studies indicate that toxins other than nicotine may be found in e-cigarettes. We don't know that. We don't know if the answer is yes, partially, or not at all. We don't know; do we? So we hold off until we know. And then we go ahead but no, some have chosen a very different course.

Given the health concerns and the lack of data substantiating health benefits, it's imperative to restrict youth exposure to e-cigarettes. Simply stated, children and teens should not be guinea pigs as we await more conclusive research. I do not understand that. I do not understand the corporate view on that. Making money is a wonderful thing, but making money with something like this where you don't know what the results are, but you do know what the results are with nicotine in cigarettes, it does not reflect well on corporate America.

Unfortunately, awareness and use of e-cigarettes by youth has been surging. So please consider the following: Between 2011 and 2012, I count that to be one year, e-cigarette use among U.S. teens more than doubled; 1,800,000 kids have tried these products; and

a recent study found that awareness of e-cigarettes among youth is virtually ubiquitous. Now I guess that means they have to see stuff somewhere, like advertising, maybe television, maybe newspapers, maybe magazines, maybe lots of it. So we'll talk about that. The growth in youth awareness and use of e-cigarettes has coincided with a flood of recent e-cigarette marketing activity.

A report published this month in the *Journal of Pediatrics* found that youth exposure to e-cigarette advertising on television increased 256% in two years. That's kind of like all the results are out on the health surveys. Just go. Go for it. Go for that dollar. 256% increase. It's extraordinary. A May American Legacy Foundation report found that last year over 14 million teens saw e-cigarette advertising on TV and 9.5 million saw printing ads.

So while major e-cigarette companies reiterate that they only target adults, a large youth audience still appears to be getting their message pretty loudly and pretty clearly, and particularly, when they aim the message in TV and magazines and, you know, social media and events, which just really come down hard toward kids.

Good morning, Senator Boxer.

Senator BOXER. Good morning. Good afternoon.

The CHAIRMAN. You can wish me a happy birthday.

Senator BOXER. And a happy birthday.

The CHAIRMAN. Thank you.

[Laughter.]

The CHAIRMAN. So to look more closely at this issue, I joined a group of Senators and Representatives including Representative Waxman, Senator Durbin—who is going to be here, when he does, he's going to be able to speak—Senator Harkin and Committee colleagues like Senator Boxer, Senator Blumenthal, and Senator Markey, in a recent investigation asking leading e-cigarette manufacturers about their marketing practices.

The results of this inquiry, and that's all it was, were troubling. The joint report we issued this April concluded that e-cigarette manufacturers are aggressively promoting their products using techniques in venues that appeal to youth. Now, I understand that whatever young people go to, you're probably going to find adults. So if you say, "We're really targeting adults," I guess, you just have to overlook the fact that a lot of adults wouldn't go to what you're targeting. But, we'll see.

Practices of surveyed companies include: Sponsorship of youth-oriented sporting and cultural events; handing out free product samples—that's really nice, you know. Free product samples. I mean, that's neutral. Nothing aggressive about that. Nothing about enticing the money flow to pick up in that. Using celebrity spokespeople; God rest their souls. Airing television ads during programs that reach large youth audiences; using social media without imposing age restrictions; and marketing e-cigarettes in flavors that could appeal to children.

Now, I'm an adult so would I be attracted to Cherry Crush, Chocolate Treat, Peachy Keen, Vanilla Dreams? No, I wouldn't. Sixty years ago, I probably would have been. So that's the way it works. The dollars flow in.

This review provided just a snapshot of activities of nine market leaders in this industry, but there are hundreds of companies that

do this in the marketplace. For example, beyond the flavors identified in our report, refillable nicotine liquid is marketed and can be found in flavors include: Bazooka Joe, no turn on for me; Gummy Bears, no, no, that's not adult stuff; Chocolate Tootsie, Tootsie, that's not adult stuff. That's aimed at children.

Products like these sound more like a candy shop display than a means for delivering nicotine vapor. And it's not hard to see how they could appeal to kids. Many of the practices that e-cigarette companies are using to pitch their products are prohibited for cigarette marketing under measures' including the comprehensive 2009 Family Smoking Prevention and Tobacco Control Act, which passed and is the law, but these restrictions do not currently, I say, apply to e-cigarettes. A loophole in the law. Chance to rake in cash. Worry about the kids later. 4,000 kids in West Virginia, well, you know, is that important or not? To me, it kind of is. To the companies, they might not be looking at that.

It's worth noting that the Tobacco Control law was enacted following years and years of litigation that uncovered internal tobacco company documents showing that, despite claims that they only promoted to adults, the industry had targeted young people as a critical market. And of course you have. That's where the money is. That's where the buying is. That's where the—got cash in your pocket and you're 12, 8, 14? Out you go. You want to be cool? Well you can actually hold one of these things and look like you're Gloria Swanson; was that her name?

In April, the FDA proposed rules to regulate e-cigarettes, but finalizing these rules could take a long time; making them complete. Meanwhile the e-cigarette industry is booming, and tobacco companies with a history of marketing cigarettes to youth have been jumping into the market. I don't know how many per day, per week. I just don't know, but a lot. As the e-cigarette industry continues to rapidly evolve, we need to hold companies, something called, accountable. Accountable. That's an American tradition. GM is finding out about that. Toyota found out about that. Accountable for promotional activities that encourage kids to start using e-cigarettes before we know what the health effects really are. Don't wait for what you might be getting into; what harm you might be doing. But jump in now and maybe Congress and FDA will be as they always are. Slow. So you can make a lot of money while we're sorting this all out. And then again, those 4,000 kids in West Virginia are not, maybe, at the top of your list.

And because e-cigarettes look so similar to cigarettes, we must also make sure that e-cigarette marketing doesn't undermine decades of work to de-glamorize and de-normalize smoking for American youth and there we are making tremendous progress; enormous progress after a long period of time.

In any event, I look forward to talking about these issues with the major e-cigarette companies represented here today and our panel's accomplished experts.

And now, Senator Thune.

**STATEMENT OF HON. JOHN THUNE,  
U.S. SENATOR FROM NORTH DAKOTA**

Senator THUNE. Thank you, Mr. Chairman.

And allow me to add my birthday wishes. Happy birthday to you. I'm sorry you're stuck spending it with us.

[Laughter.]

The CHAIRMAN. No, I'm not. I'm not at all.

Senator THUNE. Mr. Chairman, I want to thank you for holding the hearing and thank today's witnesses for appearing before the Committee.

According to the World Health Organization, there are more than one billion smokers in the world. Sadly, in one year alone, more than 5 million of those people will die prematurely due to direct tobacco use.

In 1976, Professor Michael Russell, a leading expert on cigarette addiction, wrote "People smoke for nicotine, but they die from the tar."

The introduction of e-cigarettes which usually contain nicotine but none of the tar involved in ordinary cigarettes presents new challenges for policymakers, for regulators, and for the public health community. It's also a new opportunity for increased public health to the extent that these new products may help reduce the number of individuals who smoke combustible tobacco cigarettes.

Dr. David Abrams at the American Legacy Foundation, a non-profit organization dedicated to reducing tobacco use, that is funded by payments from the Master Settlement Agreement between State Attorneys General and the tobacco industry in 1998, has called the e-cigarette a potentially "disruptive technology, able to render the combustion of tobacco obsolete."

Similarly, Mitch Zeller, Director of the Food and Drug Administration's Center for Tobacco Products, recently said "we have to have an open mind on the potential for these emerging technologies to benefit public health."

In addition, a recent study by researchers at the University College London on the efforts of people to stop smoking found that e-cigarettes are 60 percent more effective than nicotine replacement therapy, such as nicotine patches or gum. Many e-cigarette companies argue that their product is still an emerging technology and warn that restriction on e-cigarettes that do not follow the science may inhibit future innovation to create safer products for existing smokers.

At the same time, we need to be mindful that even if e-cigarettes are shown to be less harmful than combustible tobacco cigarettes, nicotine is addictive and the long-term usage and health effects of these products are currently unknown. Opponents of the product also believe that e-cigarettes are a gateway to combustible tobacco cigarettes, especially among minors.

Recent studies have shown that, with an increase in e-cigarette marketing, overall awareness of e-cigarettes is growing and some advertisements, whether they are intended to or not, are reaching youth audiences. In addition, the Campaign for Tobacco-Free Kids, represented here today by Mr. Myers, has identified e-cigarette advertisements that employ similar campaigns and themes as advertisements from combustible cigarette companies decades ago. While this is not necessarily the case for all e-cigarette companies, it raises understandable concern about the targeting of this advertising.

There has also been a recent rise in the number of calls to poison centers involving children related to e-cigarettes and the accompanying solution, which often contains nicotine and other ingredients. The American Academy of Pediatrics, represented here today by Dr. Tanski, has raised concerns about the lack of child resistant packaging on these products.

Earlier this year, the Food and Drug Administration proposed a deeming rule to regulate e-cigarettes as tobacco products. A number of questions are being asked about just how these products should be regulated, especially how they can and cannot be marketed. Given that these are relatively new products and given the extent to which they may provide benefits to public health, I believe sound science should drive any discussion of Federal regulation.

I also think we should all agree that children should not be able to purchase these products. My home state of South Dakota has banned the sale or use of e-cigarettes by those younger than 18 years of age. And several other states have done the same.

While I'm opposed to smoking in general, I look forward to learning more about the apparent potential of e-cigarettes to reduce harm to current smokers. As with most issues that we face in Congress, I believe that more scientific investigation and thoughtful discussion is needed, and Mr. Ballin is here to discuss some of his work with the University of Virginia to start a dialogue between various stakeholders on these issues.

I'd like to end with a quote from Dr. Thomas Glynn who is a director at the American Cancer Society, who sums up the current debate surrounding e-cigarettes as follows: ". . . as with so many highly celebrated or reviled products, their true nature likely lies somewhere in between, with both pros and cons to recommend or discourage their use." Hopefully we can shed some light on these pros and cons here today.

So thank you, again, to our witnesses for appearing today and I look forward to hearing your testimony.

Thank you, Mr. Chairman.

The CHAIRMAN. Let's start with Dr. Tanski.

**STATEMENT OF SUSANNE E. TANSKI, MD, MPH, FAAP,  
AMERICAN ACADEMY OF PEDIATRICS**

Dr. TANSKI. Good afternoon.

And, may I add my birthday wishes, Mr. Chairman?

The CHAIRMAN. No, please don't.

Dr. TANSKI. Happy birthday.

Dr. TANSKI. I'm Dr. Susanne Tanski, a practicing Pediatrician and Associate Professor of Pediatrics at the Geisel School of Medicine at Dartmouth. I'm here today representing the American Academy of Pediatrics, a professional membership organization of 62,000 pediatricians. I'm the Chair of the AAP's Tobacco Consortium and I conduct research on tobacco and adolescents.

Chairman Rockefeller, Ranking Member Thune, and members of the Committee, it's my pleasure to be here today to talk about electronic cigarettes. Pediatricians have numerous and growing concerns about the known and unknown risks and health impacts of e-cigarettes. We're seriously concerned that e-cigarettes may lead

adolescents to a lifetime of nicotine addiction and could serve as a gateway to traditional cigarettes.

The aggressive marketing of electronic cigarettes and its impact on youth is particularly worrisome. The evidence is clear that tobacco advertising directly influences youth. Use of e-cigarettes is rising dramatically as told and we believe this increase is clearly linked to unfettered advertising. While there's much we don't yet know about these products, we do know enough to say this: We must act now to protect children against these risks from e-cigarettes.

E-cigarettes has mentioned they're devices that heat and vaporizes solution containing nicotine, flavoring and other chemicals. Contrary to claims, these products are not without significant risk. Nicotine itself is not a benign substance. Nicotine is a psycho-active drug with a high level of toxicity and rapid addiction. Overdose of nicotine can lead to headache or dizziness, or seizures and death. It can be absorbed through the skin and it comes with workplace safety warnings to handle it with gloves, mask, goggles and protective clothing.

Due to its extreme toxicity, the estimate and lethal dose of nicotine is somewhere between 1 and 13 milligrams per kilogram of body weight. Toxic effects would be seen at much lower levels for those who are nicotine naïve like children. Pediatricians fear it's only a matter of time before a young child dies from the liquid nicotine used to refill these e-cigarettes.

Indeed, e-liquid has led to a recent spike in calls to poison control centers. E-liquid is a likely candidate for ingestion by young children because it's colorful, it often smells like candy, and it's often sold without childproof packaging. At the highest concentration, a small bottle of e-liquid can contain over 500 milligrams of nicotine. That's enough to kill several average size curious toddlers.

We find it completely unacceptable that no Federal laws or regulations currently require the sale of e-liquid in childproof containers. We call on Congress and the Administration to help us to act quickly to ensure that this needless danger to children is eliminated.

The emissions from e-cigarettes are also not harmless water vapor. The ingredients in e-liquids can cause lung irritation in the short-term and no research has yet been established to show their long-term safety. Vapor contains numerous known toxins and carcinogens albeit at levels markedly lower than that found in regular cigarettes. The levels of particulates that are emitted are similar to that in combusted cigarettes.

Flavored e-cigarettes are particularly concerning because of the well-known appeal of flavored tobacco products to youth. This 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 and piña colada."

Notably, this same company markets e-cigarettes in cherry, vanilla and piña colada. Other e-liquid flavors, as mentioned, include cotton candy, Gummy Bear, Captain Crunch, Atomic Fireball; clearly enticing children.

Young children being enticed to experiment with nicotine is concerning because the adolescent brain appears uniquely susceptible to nicotine addiction with symptoms of dependence occurring within days to weeks of intermittent nicotine use. If e-cigarettes cause nicotine addiction to adolescent, there's a risk that these users will progress to combusted tobacco products.

Anecdotal reports and limited data suggest that e-cigarettes may help many smokers or some smokers to reduce or quit smoking. At this time, further research is necessary to determine if and how e-cigarettes can play a beneficial role in reducing tobacco related disease. Research also needs to identify whether e-cigarettes are used as a bridge to the smoker's next cigarettes, delaying or inhibiting complete smoking cessation.

E-cigarettes have yet another cause for concern: the re-normalization of smoking. We know that children do what they see. It's therefore very important that we not allow e-cigarette use to re-normalize the image of a smoker.

Given all these concerns, it's alarming to us that e-cigarette use among young people is growing dramatically. A very recent study by Legacy found that 9 percent of 13 to 17 year olds are currently using electronic cigarettes. Marketing clearly plays a large role on this increase. There's substantial evidence that tobacco marketing reaches and influences adolescents.

E-cigarettes are being advertised with many of the same tools that were historically used by Big Tobacco companies: celebrity endorsements, glamorous models, and event sponsorships. They're promoted with messages that are appealing to youth: freedom, rebellion, independence. These marketing practices must stop.

America's pediatricians believe that strong regulations of e-cigarettes are absolutely essential to protect children from the risk of these products. We support FDA's regulatory authority to regulate tobacco products for the protection of the public health. It would be a tragedy if we failed to regulate e-cigarettes in a way that protects children only later to find out that we caused serious harm.

The message of America's pediatricians on e-cigarettes is simple: We have a duty first to protect the children. Thank you very much for the opportunity to speak here today.

[The prepared statement of Dr. Tanski follows:]

PREPARED STATEMENT OF SUSANNE E. TANSKI, MD, MPH, FAAP, ON BEHALF OF THE AMERICAN ACADEMY OF PEDIATRICS

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 percent in 2011 to 10.0 percent 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 percent 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 percent of 13–17 year olds had ever used an e-cigarette, and 9 percent currently used them. Among ever-cigarette users aged 13–17, 32 percent 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

<sup>1</sup>Duke JC, Lee YO, Kimm AE, Watson KA, Arnold KY, Nonnemaker JM, Porter L. Exposure to electronic cigarette television advertisements among youth and young adults. *Pediatrics* 2014; 134.

<sup>2</sup>Centers for Disease Control and Prevention. Notes from the Field: Electronic Cigarette Use Among Middle and High School Students—United States, 2011–2012. *Morbidity and Mortality Weekly Report*. September 6, 2013, 62(35):729–730.

<sup>3</sup>American Legacy Foundation. Vaporized: E-Cigarette, Advertising and Youth. Available at [http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig\\_Report-May2014.pdf](http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf) 2014. Accessed June 16, 2014.

<sup>4</sup>Benowitz NL. Nicotine Addiction. *N Engl J Med*. 2010, 362:2295–230.

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

<sup>5</sup>Material Safety Data Sheet L-Nicotine. Available at <http://www.sciencelab.com/msds.php?msdsId=9926222>. Accessed June 16, 2014.

<sup>6</sup>Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Archives of Toxicology*. 2013; 88:5-7.

<sup>7</sup>Bassett RA, Oosterhoudt K, Brabazon T. Nicotine Poisoning in an Infant. *N Engl J Med*. 2014; 370:2249-2250.

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

<sup>8</sup>Difranza JR, *et al.*, Initial symptoms of nicotine dependence in adolescents. *Tobacco Control*. 2000, 9:313–319. Difranza JR, *et al.*, Symptoms of Tobacco Dependence After Brief Intermittent Use. *Arch Pediatr Adol Med*. 2007; 161(7):704–710.

<sup>9</sup>Chen J. Millar WJ. Age of smoking initiation: implications for quitting. *Health Rep*. 1998 Spring; 9(4):39–46.

<sup>10</sup>Slotkin, TA. Nicotine and the adolescent brain: insights from an animal model. *Neurotoxicology and Teratology*. 2002;24: 369–384.

<sup>11</sup>U.S. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014 (Health consequences of nicotine exposure, pages 120–122)

<sup>12</sup>Benowitz NL. *Nicotine Safety and Toxicity*. New York: Oxford University Press; 1998.

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 allowing-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

<sup>13</sup> McMillen RC. Trends in electronic cigarette use among U.S. adults: use is increasing in both smokers and non-smokers. Social Climate Survey of Tobacco Control, Mississippi State University. Personal communication.

<sup>14</sup> Lorillard Inc. Youth Smoking Prevention Program. What you need to know about e-cigarettes—Infographic. Available at <http://www.realparentsrealanswers.com/what-you-need-to-know-about-e-cigarettes-infographic/>. Accessed June 16, 2014.

<sup>15</sup> Goniewicz ML, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J, Prokopowicz A, Jablonska-Czapla M, Rosik-Dulewska C, Havel C. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tob Control*. 2014; 23:133–139.

<sup>16</sup> Fuoco FC, Buonanno G, Stabile L, Vigo P. Influential parameters on particle concentration and size distribution in the mainstream of e-cigarettes. *Environ Pollut* 2014; 184:523–529.

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 percent 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 percent 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.

<sup>17</sup>U.S. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

<sup>18</sup>Duke JC, Lee YO, Kimm AE, Watson KA, Arnold KY, Nonnemaker JM, Porter L. Exposure to electronic cigarette television advertisements among youth and young adults. *Pediatrics* 2014; 134.

<sup>19</sup>American Legacy Foundation. Vaporized: E-Cigarette, Advertising and Youth. Available at <http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig-Report-May2014.pdf> 2014. Accessed June 16, 2014.

<sup>20</sup>Senators Durbin, Harkin, Rockefeller, Blumenthal, Markey, Brown, Reed, Boxer, Merkley, Representatives Waxman and Pallone. Gateway to Addiction. Available at [http://www.durbin.senate.gov/public/index.cfm/files/serve/?File\\_id=81d14ff7-f2f6-4856-af9d-c20c0b138f8f](http://www.durbin.senate.gov/public/index.cfm/files/serve/?File_id=81d14ff7-f2f6-4856-af9d-c20c0b138f8f). Accessed June 16, 2014.

The CHAIRMAN. Thank you very much, Dr. Tanski.  
And now, Mr. Matthew Myers.

**STATEMENT OF MATTHEW L. MYERS, PRESIDENT,  
CAMPAIGN FOR TOBACCO-FREE KIDS**

Mr. MYERS. I'm Matthew Myers, President of the Campaign for Tobacco-Free Kids. Mr. Chairman, Minority Member Thune, members of the Committee, I want to thank you for the opportunity. We worked with many of you for over a decade to help pass the law giving the Food and Drug Administration authority over cigarettes, smokeless tobacco and all other tobacco products precisely to address many of the concerns, Mr. Chairman, that you raised today.

Over the last several years, we have seen a dramatic growth in the marketing and sale of e-cigarettes. Despite the rise and the use of e-cigarettes, as you correctly noted, little is proven either about their health effects or their population impact.

Our core position is that responsibly marketed and properly regulated e-cigarettes could benefit the public health if in fact they help people switch off of cigarettes to either the exclusive use of e-cigarettes or to quit the use of nicotine all together. However, e-cigarettes pose a potential health risk to the public if they are not used by smokers or other tobacco users to stop smoking all together; if they cause children to start or re-glamourize smoking in the eyes of our Nation's children; or if they discourage smokers from quitting by providing doses of nicotine to sustain addiction rather than help people quit.

Today, as you correctly noted, as a result of the failure of the government to act swiftly and the most irresponsible action by the manufacturers and marketers of e-cigarette companies, the marketplace for e-cigarettes has turned into a true "Wild West." The rapidly growing and, today, completely unregulated e-cigarette marketplace has not only outpaced the science, the behavior of the e-cigarette industry itself raises serious concerns about the ultimate effect of e-cigarettes on the public health.

How e-cigarettes are made can also impact whether they are effective at helping people quit smoking cigarettes or whether they lead to sustained cigarette use or introduce a whole new generation to smoking. Unfortunately, it appears that a substantial segment of the industry is neither designing their products nor marketing with an eye toward reducing the number of people who smoke cigarettes.

Let me address the issue of marketing because it is the one that this hearing is about. The marketing practices, themes and images of e-cigarette manufacturers today, Mr. Chairman, exactly as you noted, are virtually the same as those used by cigarette manufacturers to successfully attract kids to smoking cigarettes for 50 years. It is a battle that we have been fighting in our slowly but significantly winning.

Yet, for e-cigarettes today, what do we see? We see celebrity spokespeople with themes like freedom in imagery like this. We see the use of sex as we saw with the cigarette companies with themes in images like this. We see placement in the "Swimsuit" issue of *Sports Illustrated* with placements of the brand name on the bikini bottom of a scantily clad model in probably the magazine that is

read by more adolescent boys than any other single magazine in the United States. We've seen a return of sponsorship of sporting events, rock concerts, attended by youth all over the country.

Now, when cigarette companies use these exact same images in these exact same places in the exact same way the impact was tragic and we're still paying for it. It was a dramatic rise in flood in youth tobacco use.

Mr. Chairman, as you correctly noted, today we're seeing a decline in cigarette smoking. But we're also seeing a rapid rise in youth use and experimentation of e-cigarettes. No one should be surprised. While it doesn't take a rocket scientist to look at these ads and figure out who they're targeted to, we in fact have a whole body of science done by the National Cancer Institute, the Institute of Medicine, the Surgeon General, and a plethora of others that have looked at these techniques in marketing and have determined that they are directly and causally related to the increase in use of cigarette smoking among kids. It defies logic, it defies science, to say the same techniques, the same ads, won't have the same impact on our nation's youth with regard to e-cigarettes.

And you're going to hear, I'm sure, that the e-cigarette manufacturers say "We don't target kids." Well, in fact, that's exactly what the cigarette companies have been saying for 50 years. To this day, they have never admitted to running a single add that targeted kids. The third prong of those eight CEOs who stood up there after they said that they didn't believe that smoking caused disease or is addiction was "We don't market to children."

Let me quote from Judge Kessler's decision in the case the Federal Government brought against the tobacco industry, sadly, 8 years after the tobacco companies promised to stop marketing to kids. And that was from Lorillard that said, "Lorillard tobacco has never marketed or sold its products to youth." This is the same company that markets blu e-cigarettes. Judge Kessler found exactly the opposite; that that was the case.

And as you've correctly said, I won't repeat, it isn't a surprise that we've just seen the dramatic rise in youth because in the last two to 3 years we have seen a fundamental change in e-cigarette marketing and a sudden fundamental change in the amount of e-cigarette marketing.

What we're seeing is a start of a potential Tsunami, because, not that e-cigarettes are good or bad, because of the behavior of e-cigarette manufacturers and marketers, that's what is causing the rise here with regards to this. So it's not a surprise we've seen the dramatic rise and it shouldn't shock us if we see that rise take off in unprecedented levels. Unless something is done to stop the kind of marketing that I've shown you.

Now the same is exactly true with flavorings. And they're asking us, as well, to turn the world upside down. The exact same flavors that you quoted, that Dr. Tanski quoted, that prompted Congress to ban the use of characterizing flavors in cigarettes are now being found in e-cigarettes and we're hearing the same thing from them. These aren't about kids, they say. Here's a bottle of e-liquid, Cinnamon Bun flavored e-liquid. I would pass it around but your fingers would stink if you did it. And I would have to caution you not to open because it says that if it touches your skin, it's toxic. If you

inhale it, it's toxic. And yet, this is being sold over the Internet with virtually no controls so that it's easily available.

Blue Cherry Crush, with this. Is it a surprise that the data is already showing an increase in youth use of these very flavors? Dr. Tanski cited a tobacco company's own website but I could cite you a string of quotes of internal tobacco industry documents and quotes that says that these flavors appeal primarily to young people.

Now whether or not they may or may not help somebody quit smoking, we don't know. But what we do know is that they appeal dramatically to young people. And unless somebody gets a handle on the marketing of these flavors, in a new study out in just the last week shows that the number of new flavors has literally exploded. And I can guarantee you nobody is testing those flavors as they would have to if they were being regulated by FDA to see whether those flavors entice kids.

In short, Mr. Chairman, this hearing comes at exactly the right time. It is an urgent need for our government to step in and protect our kids. This is not a hearing about whether or not e-cigarettes potentially have a beneficial effect. It is about the behavior of the e-cigarette companies in how they're marketing and manufacturing these products. Unless the FDA acts and acts rapidly, and unfortunately the proposed regulation doesn't even address the question of e-cigarette marketing or the flavors in e-cigarettes, so that our kids will continue to be, as you correctly said, "human guinea pigs," for an industry that has demonstrated no responsibility in how it is marketed, where it is marketed, to whom it is targeted, its products.

We urge you to take strong action to ensure that these issues are addressed.

Thank you.

[The prepared statement of Mr. Myers follows:]

PREPARED STATEMENT OF MATTHEW L. MYERS, PRESIDENT,  
CAMPAIGN FOR TOBACCO-FREE KIDS

I am Matthew Myers, President of the Campaign for Tobacco-Free Kids. The Campaign works to reduce tobacco use and its deadly toll in the United States and around the world. We advocate for public policies proven to prevent kids from smoking and other tobacco use, help smokers quit, and protect everyone from secondhand smoke.

Chairman Rockefeller and Ranking Member Thune, I appreciate the opportunity to testify today on the marketing of electronic cigarettes and its consequences for youth.

**The Debate About E-Cigarettes**

Over the last several years, there has been a dramatic growth in the marketing and sale of e-cigarettes. Despite the rise in use of e-cigarettes, little is proven about their actual health risk or their impact on overall tobacco use. Although Congress gave the FDA the authority in 2009 in the Family Smoking Prevention and Tobacco Control Act to assert its authority to regulate tobacco products not explicitly mentioned in the Act, including e-cigarettes, as of today no Federal agency regulates e-cigarettes. As a result, companies are not required to control or disclose the level of nicotine or other ingredients in these products, test them for harmful and potentially harmful constituents, and there are no restrictions on how they are marketed or to whom.

Responsibly marketed and properly regulated, e-cigarettes could benefit public health if they help significantly reduce the number of people who smoke conventional cigarettes and become sick and die as a result. However, e-cigarettes pose a potential risk to public health if they are not used by smokers and other tobacco

users to stop smoking cigarettes altogether; if they cause more people, particularly kids, to begin using nicotine products; or if they discourage smokers from quitting cigarettes. It is important to note that the scientific evidence does not indicate a health benefit if a cigarette smoker uses both e-cigarettes and regular cigarettes (dual use) or if an e-cigarette smoker simply reduces the number of cigarettes one smokes but continues to smoke cigarettes.

Today, as the result of the failure of the government to act swiftly, the market place for e-cigarettes is truly the Wild West. The rapidly growing and completely unregulated e-cigarette marketplace has outpaced the science, and the behavior of the e-cigarette industry raises serious concerns about the ultimate effect of e-cigarettes on public health if strong, thoughtful regulation is not adopted quickly over both the products and how and to whom they are marketed. It is hard to look at how e-cigarettes are made and marketed today and not be concerned.

Today's hearing focuses on the marketing of e-cigarettes, and especially the impact of current e-cigarette marketing on youth, but it is also important to recognize the significance of the failure of the FDA to act swiftly to regulate the product itself.

Nicotine is not the substance in cigarettes that causes cancer, but neither is it benign. The most recent Report of the Surgeon General issued this January documents extensively the health risks of nicotine. It found that at high enough levels nicotine can cause "acute toxicity" and is implicated in the increased risk of diseases from smoking. Nicotine exposure has long lasting consequences. It impacts fetal development and adolescent brain development.<sup>1</sup> And, of course, nicotine is highly addictive, with research indicating that young people are more susceptible and sensitive to the effects of nicotine and can often feel dependent earlier than adults.<sup>2</sup>

It is also important to recognize that the term "e-cigarette" is being used to describe literally hundreds of different products that are changing rapidly.<sup>3</sup> This means that the few studies that exist do not cover many of the products now on the market and, in the absence of FDA getting a handle on the market rapidly, there is no way to know how helpful or how dangerous the products are that are now on the market. For example, in the current unregulated environment, e-cigarettes and refill liquids are sold containing widely varying levels of nicotine with no controls.

How e-cigarettes are made can impact whether they are effective at helping people quit smoking cigarettes or whether they lead to sustained cigarette use or introduce a whole new generation to smoking. Unfortunately, it appears that a substantial segment of the industry is neither designing their products nor their marketing with an eye towards reducing the number of people who smoke cigarettes. Instead, it appears that many if not virtually all of today's products, and much of the marketing for these products, are designed to expand the e-cigarette marketplace as broadly as possible, regardless of the age or smoking status of the consumer.

### Concerns About Marketing Practices That Attract Kids

The marketing practices, themes, and images of e-cigarette manufacturers today are virtually the same as those used by the cigarette manufacturers to successfully attract kids to smoking—including many images and strategies that have become unlawful for cigarettes precisely because of their appeal to youth. Appendix A shows some illustrative examples that demonstrate:

- E-cigarette companies are using celebrity spokespeople to pitch their products. Actor Stephen Dorff, former Playboy model Jenny McCarthy and musician Courtney Love are promoting e-cigarettes just as old Hollywood stars like Gary Cooper, Marlene Dietrich and Joan Crawford once promoted cigarettes.
- E-cigarette companies are using images and themes that appeal to youth and running ads that depict e-cigarette use as a way to express masculinity, sexiness, rebelliousness, freedom and liberation.
- E-cigarette companies are reaching millions of teens by placing their ads in places with huge youth viewership, including ads on television, online, in news-

<sup>1</sup>U.S. Department of Health and Human Services (HHS), *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014, <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/>.

<sup>2</sup>HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, Centers for Disease Control and Prevention, Office on Smoking and Health, 2012 <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>;

<sup>3</sup>Brown, CJ & Cheng, JM, "Electronic cigarettes: product characterisation and design considerations," *Tobacco Control* 23:ii4–ii10, 2014.

papers, and in magazines like *Rolling Stone*, *Sports Illustrated*, *InStyle* and *Us Weekly*.

- E-cigarette companies are sponsoring youth-oriented sports and entertainment events, including auto racing and music festivals, just like cigarette companies used to do.
- Blu e-cigarettes even featured a cartoon pitchman named “Mr. Cool” on its website, reminiscent of the Joe Camel cartoon character that so effectively marketed cigarettes to kids in the 1990s.

Mr. Chairman, the investigative report you released in April with other Members of the Senate and House provided some of the most detailed evidence to date about how e-cigarette companies are marketing their products, including the use of television and radio ads, free sampling at promotional events, and use of social media.<sup>4</sup>

When cigarette companies used these marketing practices, they were extraordinarily successful in increasing the number of kids who smoke. Congress banned cigarette advertising on television in 1970 precisely because of the impact of these ads on youth. Congress banned advertising of smokeless tobacco on TV in 1986 for the same reason. All 50 states sued the tobacco industry in the mid-1990s to bring a halt to cigarette advertising practices that are virtually identical to what we now see being used to market e-cigarettes, resulting in the prohibition of many of these practices in the Master Settlement Agreement between the major tobacco companies and state Attorneys General in 1998. Just 5 years ago, Congress cited the impact of cigarette marketing on youth as one of its reasons for enacting the Family Smoking Prevention and Tobacco Control Act and instructed the FDA to adopt regulations restricting advertising of cigarettes and smokeless tobacco products. These marketing restrictions have contributed to a steep decline in cigarette smoking by youth. Just last week, CDC reported that 15.7 percent of high school students smoked cigarettes in 2013, a decline of 57 percent since the high school smoking rate peaked in 1997.<sup>5</sup>

But while we are seeing a decline in cigarette smoking among youth, we are seeing a rapid rise in youth use of and experimentation with e-cigarettes. The percentage of high school students who ever used e-cigarettes doubled in a single year, from 4.7 percent in 2011 to 10 percent in 2012. An estimated 1.78 million youth (middle and high school students) had used e-cigarettes as of 2012.<sup>6</sup> The rise took place at exactly the same time we witnessed the dramatic growth in both the amount of advertising for e-cigarettes and the explosion of e-cigarette advertising using the images and themes that are identical to those previously used for cigarettes.

No one should be surprised. The scientific evidence is overwhelming that cigarette marketing that used these same tactics, themes and images increased youth tobacco use. A comprehensive report released by the National Cancer Institute (NCI) in June 2008 and another by the Institute of Medicine of the National Academy of Sciences found a causal relationship between tobacco advertising and increased levels of tobacco initiation by youth, focusing very specifically on the type of advertising and marketing we are seeing from the e-cigarette industry today.<sup>7</sup> The 2012 Report of the Surgeon General also found that the evidence is sufficient to conclude that there is a causal relationship between advertising and promotional efforts of the tobacco companies and the initiation and progression of tobacco use among young people.<sup>8</sup>

The e-cigarette companies claim that they don’t market to kids. The sad reality is that the cigarette companies, including those now marketing e-cigarettes, have always said the same thing. As shown in Appendix B, in the case brought by the U.S. Government against the major U.S. cigarette manufacturers, Judge Kessler quoted Lorillard’s Vice-President for External Affairs as saying, “Lorillard Tobacco Com-

<sup>4</sup>Durbin, R, *et al.*, “Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Marketing to Youth,” April 14, 2014, [http://www.durbin.senate.gov/public/index.cfm/files/serve?File\\_id=a85bb717-ac5d-4835-a584-206dbdb1f856](http://www.durbin.senate.gov/public/index.cfm/files/serve?File_id=a85bb717-ac5d-4835-a584-206dbdb1f856).

<sup>5</sup>U.S. Centers for Disease Control & Prevention (CDC), “Youth Risk Behavior Surveillance—United States, 2013,” *Morbidity and Mortality Weekly Report (MMWR)* 63(No. 4), June 12, 2014.

<sup>6</sup>CDC, “Electronic Cigarette Use Among Middle and High School Students—United States, 2011—2012,” *MMWR* 62(35), September 6, 2013.

<sup>7</sup>National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use, Smoking and Tobacco Control Monograph No. 19*, NIH Pub. No. 07–6242, June 2008. Institute of Medicine (IOM), *Ending the tobacco problem: A blueprint for the nation*, Washington, D.C.: The National Academies Press, 2007.

<sup>8</sup>HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.

pany has never marketed or sold its products to youth” and others in the industry who made similar statements and then found:

*The evidence is clear and convincing—and beyond any reasonable doubt—that Defendants have marketed to young people twenty-one and under, while consistently, publicly, and falsely, denying they do so.*<sup>9</sup>

Even as Lorillard has, for example, run a provocative ad displaying the name “blu” on the bikini bottom of a scantily clad woman in this year’s swimsuit issue of *Sports Illustrated* and even more provocative and sensual YouTube videos online, it has written to FDA claiming that it does not market e-cigarettes to youth. (See Appendix C for images. See Appendix D-1 for Lorillard’s letter to FDA and Appendix D-2 for the Campaign’s response). This is straight out of the tobacco industry’s old playbook—engage in egregious behavior that impacts youth and then engage in a campaign of denial.

### Concerns about Product Appeal to Youth

It is not just the advertising that raises concerns about the impact of the current e-cigarette market on youth and other non-smokers; it is how the product itself is being manufactured. E-cigarettes are being sold in a way that maximizes their appeal with little regard to the effect on public health. The use of flavorings is a prime example. E-cigarettes and e-liquids come in an ever growing variety of flavors, including fruit-and candy-flavors, that cigarette companies are prohibited from using. E-cigarette liquids come in flavors such as vivid vanilla, Cinabon, cherry crush, chocolate, jolly rancher, gummi bear, bubble gum, and cotton candy and many others (see Appendix C for examples).

Congress explicitly banned the use of cigarettes with similar characterizing flavors because of their appeal to youth. Before cigarettes with fruit-and candy-flavors were prohibited, they were most attractive to the youngest smokers and were being used primarily by younger smokers. One study found 22.8 percent of 17 year old smokers and 21.7 percent of 18 and 19 year old smokers used flavored cigarettes while only 9 percent of 24–26 year olds did.<sup>10</sup> Similarly, youth and young adults prefer cigar brands that come in a variety of flavors, and that preference declines significantly with age. According to a recent study, 95 percent of 12–17 year old cigar smokers reported a usual brand that makes flavored cigars compared with 63 percent of cigar smokers aged 35 and older.<sup>11</sup>

The addition of fruit and candy flavorings to e-cigarettes creates the very real possibility of broadening the appeal of this product to non-smokers who find the flavor of tobacco distasteful, including kids. Given the rapidity with which new flavors are being introduced and by whom, it is almost certain that no one is testing these products to insure that they do not appeal to youth.

Once again the industry claims that flavored e-cigarettes don’t appeal to kids and are about making the product for long term committed smokers. However, Lorillard’s own youth prevention website acknowledges, “Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, pina-colada and berry.” Three of these flavors are also offered by Lorillard’s blu (see Appendix C).

It is not just the flavors that are of concern. Three decades ago, the smokeless tobacco industry recognized one way to attract youth was to introduce them to mild, low nicotine products and then “graduate” them to stronger products. Internal company documents show that United States Tobacco developed a strategy for hooking new spit-tobacco users (meaning kids) some time ago. As one document states:

*New users of smokeless tobacco—attracted to the category for a variety of reasons—are most likely to begin with products that are milder tasting, more flavored, and/or easier to control in the mouth. After a period of time, there is a natural progression of product switching to brands that are more full-bodied, less flavored, have more concentrated “tobacco taste” than the entry brand.*<sup>12</sup>

We may well be seeing the same tactic with regard to e-cigarettes. When tested, many e-cigarettes appear to have far less nicotine than is needed to satisfy the craving of an addicted cigarette smoker but have a mild enough taste to be easy to use

<sup>9</sup>U.S. v. Philip Morris USA, Inc., 449 F.Supp.2d at 691.

<sup>10</sup>Klein, S *et al.*, “Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004–2005,” *Nicotine and Tobacco Research*, 10(7):1209–14, July 2008.

<sup>11</sup>Delnevo, C, *et al.*, “Preference for flavoured cigar brands among youth, young adults and adults in the USA,” *Tobacco Control*, [Epub ahead of print], April 10, 2014.

<sup>12</sup>Connolly, GN, “The Marketing of Nicotine Addiction by One Oral Snuff Manufacturer,” *Tobacco Control* 4(1):73–79, Spring 1995.

for a non-smoker. This poses two concerns: Are products being made that make it easy for an adolescent non-smoker to use? Are they also being made with too little nicotine to serve as an effective tool to help a cigarette smoker quit, but just enough to enable a cigarette smoker to use these products when they are in places where they cannot smoke to serve as a bridge that enables them to maintain their cigarette addiction?

### Recent Studies on Youth Viewership of E-Cigarette Advertisements

E-cigarette companies say they are marketing their products only to adults. But we should pay attention to what they do, not just what they say. A look at the numbers tells a different story. Recent studies have found that advertising by e-cigarette companies is reaching many youth and young adults.

In a recent report detailing the results of a survey of youth and young adults, Legacy found that 60 percent of teens 13–17 years old said they saw e-cigarette advertising at convenience stores and similar retail outlets always, most of the time, or some of the time; 45 percent said they saw e-cigarette advertising on TV always, most, or some of the time; and 43 percent saw e-cigarette advertising online always, most, or some of the time. Viewership of these forms of e-cigarette advertising was even higher among young adults 18–21 years of age.<sup>13</sup>

A second study in the Legacy report analyzed media expenditure data to estimate whether e-cigarette advertising was reaching young people. It estimated that 58 percent of teens ages 12–17 (14.1 million) were exposed to e-cigarette ads on TV. E-cigarette ads ran on a number of networks including Comedy Central, USA, ABC Family, Bravo, E!, MTV, VH1, and Spike. And ads were run on programs featuring mature cartoons such as *South Park* and *Futurama*, reality shows like *Bar Rescue* and *COPS*, and sitcoms like *The King of Queens*. Legacy's analysis also found that 39 percent of teens ages 12–17 (9.5 million) were reached through e-cigarette ads in magazines. Top magazines featuring these ads included *Star*, *OK!*, *Entertainment Weekly*, *Us Weekly*, *Men's Journal*, and *Rolling Stone*.<sup>14</sup>

Researchers at RTI published a recent study in the journal *Pediatrics* that found that youth (12–17 years old) exposure to e-cigarette television ads increased 256 percent from 2011 to 2013, and young adult (18–24 years old) exposure increased 321 percent of that time period. The study also estimated that youth exposure to e-cigarette television ads was extensive—the equivalent of 50 percent of 12–17 year olds viewing an average of 21 ads from October 2012 to September 2013. It found that cable network AMC, Country Music Television, Comedy Central, WGN America, TV Land, and VH1 aired the most e-cigarette ads in 2013, and e-cigarette ads appeared on programs that were among the 100 highest-rate youth programs for 2012–2013, including *The Bachelor*, *Big Brother*, and *Survivor*.<sup>15</sup>

### The Growing Presence of Big Tobacco in the E-Cigarette Marketplace

Both the Legacy and RTI studies noted that blu e-cigarettes, owned by the cigarette company Lorillard, was by far the largest spender on advertising. This raises concern about what will happen when the other cigarette companies fully enter the e-cigarette marketplace. Altria and Reynolds American have successfully test-marketed their e-cigarettes and are rolling out nationwide campaigns this year to promote them.<sup>16</sup> If they follow a marketing strategy similar to the one Lorillard has used for blu, the amount of e-cigarette advertising is likely to expand dramatically and result in high numbers of youth exposed to e-cigarette ads.

The growing dominance of Big Tobacco companies in the e-cigarette market should make us all skeptical of any claims they make about only marketing to adults.

### FDA Must Move More Rapidly to Exercise its Authority to Address E-Cigarette Marketing

When Congress enacted the Family Smoking Prevention and Tobacco Control Act in 2009, it recognized the harm to public health that can arise from the manufacture, marketing and sale of tobacco products not directly addressed in the legislation, including e-cigarettes, and gave FDA the authority to assert its authority over all other tobacco products, including the authority to restrict the advertising and

<sup>13</sup> Legacy, *Vaporized: E-Cigarettes, Advertising, and Youth*, April 2014.

<sup>14</sup> Legacy, *Vaporized: E-Cigarettes, Advertising, and Youth*, April 2014.

<sup>15</sup> Duke, JC, "Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults," *Pediatrics* [Epub ahead of print] pii: peds.2014-0269, June 2, 2014.

<sup>16</sup> Esterl, M, "Altria To Launch MarkTen E-Cigarette Nationally," *The Wall Street Journal*, February 19, 2014. Citi, "Start Spreading the Vuse: National Launch Slated for 2014," November 18, 2013.

promotion of these tobacco products if the Secretary of Health and Human Services determines such regulation is appropriate for the protection of the public health.<sup>17</sup>

In April, after three full years of internal deliberation, FDA issued a proposed rule that would assert its authority over e-cigarettes and other tobacco products not currently regulated by FDA, but that proposed rule does not include any marketing, including flavoring, restrictions for e-cigarettes.<sup>18</sup> As a result, it could be years more before FDA even begins to grapple with what restrictions should be placed on e-cigarette marketing to protect youth and the public health. It also means that marketing restrictions that FDA applies today to cigarettes—such as no branded sponsorship of athletic or musical events, no distribution of non-tobacco merchandise carrying a tobacco product logo and restrictions on flavorings—will not apply to e-cigarettes any time in the foreseeable future unless significant changes are made to the proposed rule before it is finalized.

FDA has claimed that it cannot address the issue of marketing for e-cigarettes until after it has issued a final rule asserting jurisdiction over these products. It is true that FDA cannot actually impose any restrictions on e-cigarette marketing until it finalizes its pending rule, but there is nothing that prevents FDA from fully investigating current e-cigarette marketing practices and proposing specific restrictions to protect the public that can be finalized either as part of the pending final rule or immediately thereafter. Indeed, to do anything else leaves our children vulnerable to the most unscrupulous e-cigarette marketing.

As a first step, FDA should establish a record to support the necessary regulation of marketing restrictions on e-cigarettes. Based on the information that is publicly available, it is our view that the record will support the application to e-cigarettes the same marketing restrictions it currently applies to cigarettes, either by incorporating them during the current rulemaking process or starting a new rulemaking process that will be finalized shortly after FDA issues a final rule asserting jurisdiction over e-cigarettes.

Regardless of how one weighs the potential benefits and risks of e-cigarettes, all should be able to support policies that will reduce the likelihood of young people using them. Leaving it to the industry to police itself has led to a situation that puts our Nation's youth at risk and could reglamorize smoking to youth, undermining the progress that has been made over the last 30 years.

If e-cigarettes are to provide a benefit to public health, they must be marketed only to adult cigarette smokers, not youth or adults who are tobacco-free.

Thank you for the opportunity to testify today.

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<sup>17</sup> 21 U.S.C. 387a. 21 U.S.C. 387f(d).

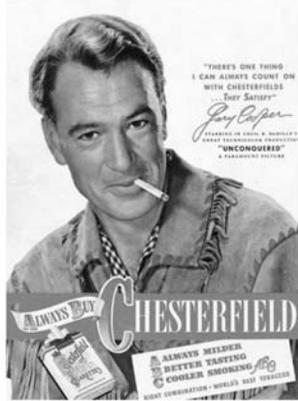
<sup>18</sup> "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," U.S. Federal Register 79(80):23142–23207, April 25, 2014.

APPENDIX A—E-CIGARETTE COMPANIES ARE COPYING BIG TOBACCO’S PLAYBOOK

There has been an explosion in e-cigarette marketing in recent years, and e-cigarette manufacturers are using the same slick tactics and imagery long used to market regular cigarettes to kids. These are just a few examples of how e-cigarette companies are copying Big Tobacco’s marketing playbook.

**1. Use of celebrity spokespeople**

Like cigarette ads of old, television, online and print ads for e-cigarettes feature catchy slogans and celebrity endorsers.



1948



2012



1950



2013

**2. Images and themes that appeal to youth**

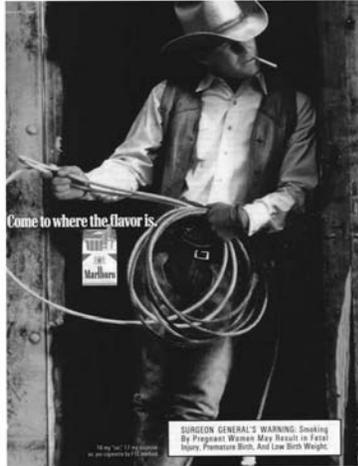
These ads feature today's equivalents of the Marlboro Man and the Virginia Slims woman, depicting e-cigarette use as masculine, sexy, or rebellious. E-cigarette ads have appeared on television, online, in newspapers, and in magazines that reach millions of teens, including *Rolling Stone*, *Sports Illustrated*, *InStyle*, and *Us Weekly*.

1989

2011

1941

2013



1996



2013

### 3. Sex sells

Like cigarette companies have long done, e-cigarette makers portray use of their products as sexually attractive.



2000



2012

**4. Use of cartoons**

The website for blu cigs has featured a cartoon pitchman named “Mr. Cool.” It was reminiscent of the Joe Camel cartoon character that so effectively marketed cigarettes to kids in the 1990s.



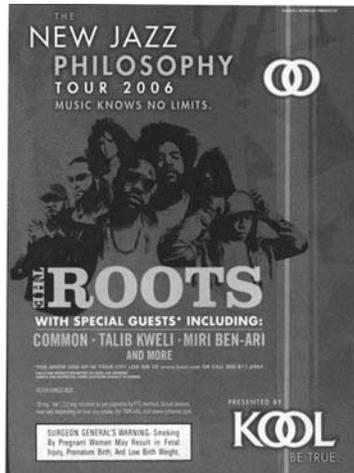
1989

2013

**5. Sponsorships**

For decades tobacco companies used sponsorships of sports and entertainment events, especially auto racing and music festivals, to promote cigarettes to huge audiences, including kids. Cigarette sponsorships are now banned, but e-cigarette brands have auto racing sponsorships of their own.

*Sponsorship of Music Events*



2006



2013

Sports Sponsorships



Formula One, 1974-1996



Formula One, 2013



Formula One, 2014



NASCAR, 1997



NASCAR, 2012

6. Redeemable Points Program



1994

|  |   |  |
|--|---|--|
| <p>Limited Edition blu Whiskey Set<br/>6,000 points<br/>Add to Wishlist</p>                        | <p>blu - iPad blu® cover<br/>2,000 points<br/>Add to Wishlist</p>             | <p>blu - 10 Bottle Soft Sided Cooler<br/>2,000 points<br/>Add to Wishlist</p>                          |
| <p>blu Plastic Stool<br/>2,000 points<br/>Add to Wishlist</p>                                      | <p>blu - iPad® cover<br/>2,000 points<br/>Add to Wishlist</p>                 | <p>Women's blu Wranch Jogger - Take Back Your Freedom (Black)<br/>1,000 points<br/>Add to Wishlist</p> |
| <p>Men's VAP blu - Take Back Your Freedom with blu (Grey)<br/>1,500 points<br/>Add to Wishlist</p> | <p>blu Shaker® Filtered Water Bottle<br/>1,500 points<br/>Add to Wishlist</p> | <p>blu's blu Vertical™ Jogger (Black)<br/>1,500 points<br/>Add to Wishlist</p>                         |

2014

**7. Images of Doctors**



Clip from The Doctors, 2010

**Doctors Endorsement Boost Sales for E-Cigarettes**

After the popular medical program "The Doctors" aired promoting the use of electronic cigarettes as a healthy alternative to traditional cigarettes, sales for electronic cigarettes "dramatically increased" according to CEO of South Beach Smoke Chris Maher.

Press Release from South Beach Smoke, November 16, 2010

**8. "Switch, Don't Quit" messages**

Tobacco companies have long tried to discourage smokers from quitting by marketing cigarette changes as reducing health risk. Some e-cigarette ads carry a similar message.



1976



2011

APPENDIX B—EXCERPTS FROM DOJ JUDGE GLADYS KESSLER’S FINAL OPINION IN *U.S. v. PHILIP MORRIS USA, INC., ET AL.*, No. 99–CV–02496GK (U.S. DIST. CT., D.C.), AUGUST 17, 2006

2637. Moreover, smokers are remarkably brand-loyal. LeVan PD, *United States v. Philip Morris*, 6/25/02, 225:3–228:12, 229:4–230:11 (“premium tobacco brands and smokers are very highly loyal and. . . they don’t switch brands very often.”). Defendants realize that they need to get people smoking their brands as young as possible in order to secure them as lifelong loyal smokers. As Bennett LeBow, President of Vector Holdings Group, stated, “if the tobacco companies really stopped marketing to children, the tobacco companies would be out of business in 25 to 30 years because they will not have enough customers to stay in business.” LeBow WD, 63:16–64:1.

2782. On June 2, 1966 Lorillard sent a letter authorizing Grey Advertising to conduct a “Penetration/Usage/Image” study designed to examine the success of Kent and True marketing. The letter indicated that the study’s results “will be tabulated out for the age cell of 16 thru 20 years, in order that we may analyze this group separately.” 89834271–4271 (U.S. 20943).

2789. An August 30, 1978 Lorillard memorandum from Ted Achey, Lorillard’s Director of Sales in the Midwest, to company President Curtis H. Judge regarding “Product Information,” demonstrates that Lorillard recognized the significance of the underage market to the company:

The success of NEWPORT has been fantastic during the past few years. Our profile taken locally shows this brand being purchased by black people (all ages), young adults (usually college age), but the base of our business is the high school student. NEWPORT in the 1970s is turning into the Marlboro of the 60s and 70s. It is the “In” brand to smoke if you want to be one of the group. Our problem is the younger consumer that does not desire a menthol cigarette. If that person desires a nonmenthol, but wants to be part of the “In” group, he goes to Marlboro. . . . I think the time is right to develop a NEWPORT NATURAL (non-menthol) cigarette to attract the young adult consumer desiring a non-menthol product. . . . A good test area might be the Camden, New Jersey Division.

03537131–32 (U.S. 22357).

3264. Steven C. Watson, Lorillard Vice President, External Affairs, was responsible for issuing a press release in 2001, stating “Lorillard Tobacco Company has never marketed or sold its products to youth.” The release was transmitted electronically by e-mail from North Carolina to P.R. Newswire in New York, and distributed from there by wire to various news agencies, to be published in newspapers, magazines or similar publications. Watson PD, *United States v. Philip Morris*, 4/2/02, 190:5–191:6.

### Conclusions

3296. The evidence is clear and convincing—and beyond any reasonable doubt—that Defendants have marketed to young people twenty-one and under while consistently, publicly, and falsely, denying they do so. Dolan WD, 24:3–16; Krugman WD, 17:2–19:1; Chaloupka WD, 30:832:20; Biglan WD, 100–379.

3302. In the face of this evidence, Defendants have denied, over and over, with great self-righteousness, that they have marketed to youth.

APPENDIX C

*Image 1.* Blu uses provocative images in an advertisement for blu e-cigarettes placed in the March 2014 Swimsuit issue of *Sports Illustrated* and an online video available through blu's YouTube channel.



Image 2. There are thousands of e-cigarette liquid flavors available in stores and online, including flavors that can be mixed according to users' tastes. These are just some of the kid-friendly options for sale.



Banana Split



Cotton Candy



"Kool-Laid" Grape



Skittles



Sweet Tart



Gummi Bear



"Fruity Loops"



Rocket Pop



Hawaiian Punch

Image 3. Lorillard's "Real Parents Real Answers" youth prevention website features an infographic on e-cigarettes, including a statement that "kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, piña-colada and berry." For comparison, Lorillard's blu e-cigarette brand offers flavor cartridges for sale on its website, including cherry, vanilla, and piña colada.

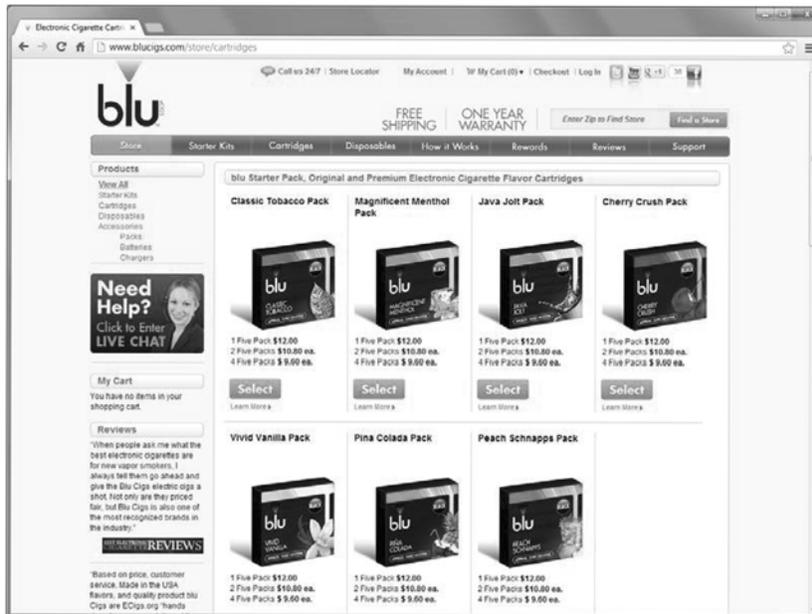


Image 4. Billboards by an e-cigarette company and a vape shop.

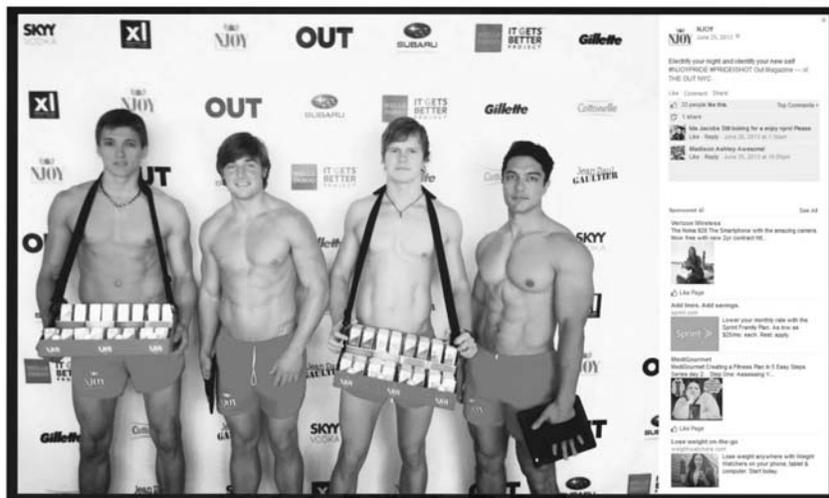


Billboard off of I-95 South in Miami, FL, December 2013



Billboard in Janesville, WI, June 2014

Image 5. E-cigarette companies use attractive and scantily-clad models to promote their products.



## APPENDIX D-1

LORILLARD, INC.  
Greensboro, NC, October 23, 2013

Hon. MARGARET HAMBURG,  
Commissioner,  
U.S. Food and Drug Administration,  
Silver Spring, MD.

RE: FDA REGULATION OF E-CIGARETTES

Dear Commissioner Hamburg,

On behalf of Lorillard Inc., the owner of blu eCigs, the leading electronic cigarette company in the United States, I am writing to express our agreement with many of the principles expressed by state Attorneys General who urged the Food and Drug Administration (FDA) on September 24, 2013,<sup>1</sup> to assert its authority to regulate electronic cigarettes under the Tobacco Control Act.

Lorillard agrees that FDA is authorized to regulate e-cigarettes. Since acquiring blu eCigs in April 2012, Lorillard repeatedly has stated that it stands ready to work with FDA to develop regulations for e-cigarettes. Lorillard has reiterated this publicly and in private meetings with FDA.

E-cigarettes are a product that has the potential to play a critical role in the national harm reduction discussion. For too many years, tobacco policy has been mired in an all-or-nothing philosophy. Under this approach, smokers are presented with just one alternative: quit. This mindset has prevented the implementation of a comprehensive public health strategy designed to reduce tobacco-related disease.

E-cigarettes are distinctly different from combustible tobacco cigarettes in that e-cigarettes have no tobacco smoke, no ash, no odor and no combustion, resulting in virtually none of the chemicals present in cigarette smoke. On the other hand, e-cigarettes are similar to combustion cigarettes, in that they mimic the behavior of traditional smoking.

Making less harmful products available to smokers as soon as possible should be a top priority for policy makers. We should arrive at a place where regulations mirror the continuum of risk. Regulation should promote the development of products that significantly reduce exposure to harm in the users of tobacco products. These and other regulatory actions by the FDA should encourage cigarette smokers to switch to e-cigarettes.

FDA rules should ensure the adoption of quality standards and good manufacturing practices, accompanied by a regulatory framework that ensures sales and marketing to youth is prohibited. In the meantime, absent regulations, blu eCigs has voluntarily implemented many responsible measures concerning the conduct of our business, while pressing state governments for sales restrictions that prevent youth access.

*To be clear: We agree that electronic cigarettes are not a product for youth. Any usage of electronic cigarettes by youth is unacceptable;* electronic cigarettes are intended to be used as an alternative to combustion cigarettes by smokers of legal age, and should not be sold or used by anyone under age 18.

However, it is disturbing that the Attorneys General and others in the public health community are relying on their 1990s tobacco playbook and raising the specter of youth usage of electronic cigarettes as a reason for FDA to ban or adopt draconian restrictions on the marketing and sale of these tobacco alternatives. In fact, concerns that youth are using electronic cigarettes at alarming rates are not supported by evidence.

In their letter the state Attorneys General cite a recent report by the Centers for Disease Control and Prevention (CDC) as proof that youth are taking up the use of e-cigarettes at alarming rates. The CDC study claimed that electronic cigarette use had more than doubled among middle and high school students from 2011 to 2012. This report's "conclusion" has led many to call for the ban on the sale of electronic cigarettes, or at the least the imposition of drastic marketing and sales restrictions that may cause adult smokers to forgo the opportunity to switch from smoking to vaping. Yet the CDC study did not offer evidence, nor are we aware of any such evidence, of an epidemic of youth usage of electronic cigarettes at all.

The CDC survey showed that 2.1 percent of the youth had experimented with e-cigarettes. It did not report daily or regular use statistics for e-cigarettes. In other

<sup>1</sup>National Association of Attorneys General. FDA Regulation of E-Cigarettes. Sept. 24, 2013. Letter to The Honorable Margaret Hamburg. <http://www.naag.org/ags-urge-fda-to-regulate-sale-and-advertising-of-e-cigarettes.php>

words, the statistic reported by CDC includes youth who took only so much as one puff from an e-cigarette and may not have used the product ever again. This means that the CDC's claim that electronic cigarette use has doubled among underage youth is likely dramatically overstated. As far as we know from that survey, none of them are using e-cigarettes daily, in contrast with the unfortunate fact that many more youth continue to regularly smoke combustible cigarettes.

Unfortunately, the CDC has claimed that its survey shows that kids are starting with e cigarettes and then progressing to smoke combustion cigarettes. This is not supported by the scientific evidence. Dr. Michael Siegel, professor in the Department of Community Health Sciences, Boston University School of Public Health, has said the statement is a "fabrication" and that "the study did not document any examples of youth starting to smoke as a result of first trying electronic cigarettes." Furthermore, Siegel notes that the "among youth who experimented with electronic cigarettes in 2012, the overwhelming majority—90.6 percent—were smokers."

Lorillard supports reasonable, science based regulations of e-cigarettes. However, that regulation must not have the effect of denying the harm reduction benefits of electronic cigarettes to smokers looking for an alternative. We think there is an opportunity to enact sensible regulation to accomplish this.

After its acquisition of blu eCigs, Lorillard made a commitment to take a leadership role in shaping how manufacturers in this emerging category can be responsible. We agree that e cigarettes should not be marketed, sold, or used by anyone younger than 18 years of age, and have demonstrated our commitment to this in the following ways:

#### **1. Two-Step Age Screening Process on blu eCigs Website**

blu eCigs prohibits the sale of e-cigarettes to anyone younger than 18 years of age through strict age-verification and third party certification procedures on websites or through vendor verification in stores.

Since its acquisition by Lorillard, blu eCigs has implemented a two-step age screening process on its website. The website screening process begins with a self-certification of age. Before being allowed access to the website, the person is asked to certify that he or she is 18 years of age or over. Only individuals certifying they are 18 years of age or older are permitted entry. To purchase any product from the website, a consumer must first provide personal information, including first and last name, address and date of birth. Then two third-party age verification systems compare this information to public records to verify the consumer's identity and that the consumer is 18 years of age or older. If either system verifies the consumer's identity and that the consumer is 18 years of age or older, the transaction is completed. If neither system can verify these facts, the transaction is terminated. This rigorous screening process established by blu eCigs prevents persons under 18 years of age from purchasing blu products on its website.

However, the sale of e-cigarettes to persons under 18 years of age in a face to face transaction at retail stores is still possible in several states that do not make it illegal for retailers to sell, furnish and distribute electronic cigarettes to minors. As a result, Lorillard has strongly advocated and worked for state legislation to prevent the sale or distribution of electronic cigarettes to minors. It is an important step that states can and should take, and we urge the Attorneys General to support these statutes.

#### **2. Marketing Targeted at Consumers of Legal Age**

Responsible e-cigarette manufacturers, including blu eCigs, do not market to youth. Lorillard understands the sensitivity associated with advertising and marketing campaigns and their potential influence on minors. For this reason, blu eCigs is actively and effectively ensuring that its advertising is directed at adult smokers.

blu has run two advertisements on television. The advertisements were placed on television shows whose content is directed to viewers who are 18 years of age or older and shown during time slots when at least 85 percent of the target audience is 18 years of age or older. The advertisements were designed primarily to educate smokers regarding e-cigarettes and included two celebrities. Both celebrities are over 40 years old and have an adult target audience well beyond 18 years of age.

The Attorneys General also assert that flavored electronic cigarettes attract youth to these products. However, it is commonplace for products marketed to adults to be offered in a variety of flavors. Beer and alcohol are available in numerous types of flavors enjoyed by adults, as are many types of coffee and tea. Most notably, nicotine therapy products are also sold in a variety of flavors. For example, flavors of Nicorette gums and lozenges include White Ice Mint, Fruit Chill, Cinnamon Surge and Cherry. While Congress did ban cigarettes with a characterizing flavor other than tobacco or menthol through the Family Smoking Prevention and Tobacco Con-

trol Act, Congress did not ban characterizing flavors for other tobacco products, and FDA should not do so with electronic cigarettes. We believe we can and do market and advertise blu eCigs in a responsible manner to adult consumers so that all adults who prefer these flavors may continue enjoying them. Depriving adults the right to use flavored electronic cigarettes may very likely prevent traditional smokers from switching away from combustible cigarettes, resulting in many continuing on a lifelong path of using the most harmful of nicotine products.

We believe strongly that responsible marketing parameters that prohibit marketing and sales to youth can be achieved without suppressing adult access to what may be the most significant harm reduction opportunity ever for traditional smokers.

Lorillard again welcomes the voices of the 40 state Attorneys General in urging FDA to issue proposed regulations to assert regulatory oversight of e-cigarettes.

Lorillard encourages the FDA to ensure appropriate and reasonable regulation of e-cigarettes through policies developed by the FDA and industry in partnership. Like the Attorneys General, Lorillard looks forward to working collaboratively with the FDA to devise a reasonable, scientifically based regulatory framework covering e-cigarettes that does not stifle what may be the most significant harm reduction opportunity ever for traditional smokers.

Sincerely,

RONALD S. MILSTEIN,  
*Executive Vice President,  
Legal and External Affairs,  
General Counsel and Secretary.*

cc: James McPherson, Executive Director, National Association of Attorneys General  
All States' Attorneys-General

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APPENDIX D-2

CAMPAIGN FOR TOBACCO-FREE KIDS  
*Washington, DC, November 19, 2013*

Hon. MARGARET HAMBURG,  
Commissioner,  
U.S. Food and Drug Administration,  
Silver Spring, MD.

RE: LORILLARD LETTER ON FDA REGULATION OF E-CIGARETTES

Dear Commissioner Hamburg:

On October 23, 2013, Lorillard Inc., which owns blu eCigs, submitted to you a letter expressing support for Food and Drug Administration (FDA) regulation of electronic cigarettes (e-cigarettes). In its letter, Lorillard insists that e-cigarettes are not a product for youth and claims to have voluntarily implemented “responsible measures” to prevent the sale and marketing of e-cigarettes to youth. At the same time, however, the company questions new research by the Centers for Disease Control and Prevention (CDC) that shows a sharp increase in youth use of e-cigarettes.<sup>1</sup>

Lorillard’s attack on CDC’s research is unwarranted, and its claim of corporate responsibility with respect to youth access to its products is utterly misleading.

**Youth Use of E-Cigarettes Has Increased**

The CDC recently reported that youth use of e-cigarettes among high school students more than doubled from 2011 to 2012 (from 4.7 percent to 10 percent). The CDC estimates that nearly 1.8 million U.S. youth (grades 6–12) had tried e-cigarettes as of 2012, and 160,000 of those who tried e-cigarettes had never used conventional cigarettes.<sup>2</sup> This is a significant and alarming trend and suggests that e-cigarettes may be encouraging greater youth experimentation with tobacco products. Rather than recognizing the adverse implications of these findings for public health, Lorillard dismisses the CDC findings as “dramatically overstated” and lacking evidence. Lorillard’s absence of concern for this documentation of underage use of e-

<sup>1</sup>See October 23, 2013 Lorillard letter to Commissioner Hamburg regarding FDA regulation of e-cigarettes

<sup>2</sup>Centers for Disease Control and Prevention (CDC). “Electronic Cigarette Use Among Middle and High School Students—United States, 2011–2012,” *Morbidity and Mortality Weekly Report (MMWR)*, 62(35):729–730, September 6, 2013.

cigarettes is troubling and at odds with its claims of being a responsible manufacturer.

Like cigarettes, e-cigarettes contain nicotine; and nicotine is extremely addictive. Kids and adolescents are more susceptible to the effects of nicotine, because they are still going through critical periods of growth and their brains are still developing.<sup>3</sup> Research shows that youth can experience symptoms of dependence—including withdrawal and tolerance—after minimal exposure to nicotine.<sup>4</sup> Thus, e-cigarettes could serve as a gateway to nicotine addiction and increase kids' risk of initiating other tobacco products.

As a result of nicotine addiction, approximately three out of four teen smokers end up smoking into adulthood, even if they intend to quit after just a few years.<sup>5</sup> Research also shows that the earlier a young person first tries smoking, the higher his or her chances of ultimately becoming a regular smoker, and the less likely he or she is to quit.<sup>6</sup> Lorillard dismisses CDC's data, asserting that it "includes youth who took only so much as one puff from an e-cigarette" but, as FDA's Tobacco Products Scientific Advisory Committee has stated, "Regular cigarette smoking begins with experimentation."<sup>7</sup> The sharp increase in experimentation with e-cigarettes and its potential to draw youth into a lifetime of addiction is, therefore, a cause for great concern and worthy of more serious attention, and responsive action, than shown by Lorillard.

#### E-Cigarette Marketing Targets Youth

Lorillard states in its letter that "Responsible e-cigarette manufacturers, including blu eCigs, do not market to youth." Unfortunately, Lorillard's actions contradict its words. The marketing strategies Lorillard uses to promote blu are the same as the marketing strategies that have long been used by tobacco companies to market cigarettes to kids. They include:

- *Kid-friendly flavors:* Lorillard is the only one of the top three e-cigarette manufacturers to sell its product in flavors. In addition to classic tobacco and menthol varieties, blu e-cigarette cartridges are available in candy and fruit flavors, like cherry crush, vivid vanilla, piña colada, and peach schnapps. (See Exhibit A.) Tobacco companies have regularly used flavored products to appeal to youth, who may otherwise be turned off by the harsh taste of nicotine. It was for that reason that Congress approved the prohibition on flavored cigarette sales when it passed the Family Smoking Prevention and Tobacco Control Act in 2009. Current research confirms that flavored tobacco products are particularly popular among youth. A recently published national study found that 42.4 percent of youth smokers use flavored little cigars or flavored cigarettes.<sup>8</sup> Data from the 2013 Florida Youth Tobacco Survey show that 18.7 percent of high school stu-

<sup>3</sup>U.S. Department of Health and Human Services (USDHSS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012. See also USDHSS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2010.

<sup>4</sup>USDHSS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2010.

<sup>5</sup>USDHSS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.

<sup>6</sup>See, e.g., Khuder, SA, *et al.*, "Age at Smoking Onset and its Effect on Smoking Cessation," *Addictive Behavior*, 24(5):673-7, September-October 1999; D'Avanzo, B, *et al.*, "Age at Starting Smoking and Number of Cigarettes Smoked," *Annals of Epidemiology*, 4(6):455-59, November 1994; Chen, J & Millar, WJ, "Age of Smoking Initiation: Implications for Quitting," *Health Reports*, 9(4):39-46, Spring 1998; Everett, SA, *et al.*, "Initiation of Cigarette Smoking and Subsequent Smoking Behavior Among U.S. High School Students," *Preventive Medicine*, 29(5):327-33, November 1999; Breslau, N & Peterson, EL, "Smoking cessation in young adults: Age at initiation of cigarette smoking and other suspected influences," *American Journal of Public Health*, 86(2):214-20, February 1996.

<sup>7</sup>Tobacco Products Scientific Advisory Committee, "Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations" (July 21, 2001), at 215.

<sup>8</sup>King, B, *et al.*, "Flavored-Little-Cigar and Flavored-Cigarette Use Among U.S. Middle and High School Students," *Journal of Adolescent Health*, August 27, 2013. Flavored cigarettes may include menthol products.

dents have tried a flavored tobacco product at least once.<sup>9</sup> It is reasonable to expect that flavored e-cigarettes would appeal to youth in the same way as other flavored tobacco products.

- *Magazine advertisements:* Lorillard regularly places advertisements for blu in magazines with high youth readership, including *Rolling Stone*, *ESPN The Magazine*, and *Sports Illustrated*. (See Exhibit B.) Youth readership (ages 12-17) for these three magazines alone is more than five million; the reach for all magazines would be millions more.<sup>10</sup> With images of rugged men, glamorous women, and depictions of e-cigarette use as masculine, sexy, and rebellious, these advertisements likely appeal to many teenage boys and girls.
- *Celebrity endorsements:* Lorillard’s advertisements for blu feature TV personality Jenny McCarthy and actor Stephen Dorff. Lorillard may be right that both celebrities are over 40 years old, but they are pictured in trendy settings, such as night clubs, speaking about the ways in which blu enhances their social and dating lives—scenes and topics that are familiar and important to many youth. This strategy mirrors tobacco companies’ strategies from the 1940s and 1950s, when they used celebrities to associate a specific lifestyle and personality with their cigarettes in an effort to construct positive social norms around smoking.<sup>11</sup> And while Lorillard asserts that its TV advertisements featuring these celebrities were shown during time slots when at least 85 percent of the viewing audience was 18 years of age or older, it neglects to mention that these advertisements also are posted on YouTube, a public video-sharing website that is popular with youth. (See Exhibit C.) As such, these advertisements—which associate glamour with the use of blu—can be viewed by individuals of all ages at any time.
- *Sports, music, and other event sponsorships:* Although Federal law prohibits Lorillard from sponsoring sporting and music events with its cigarette brands, it continues to take advantage of these popular, youth-friendly events to market blu. (See Exhibit D.) Blu currently sponsors cars in the IndyCar and Nascar circuits. It has sponsored numerous musical festivals, including The Governors Ball Music Festival in New York City, June 2013; the Bonnaroo Music and Arts Festival in Tennessee, June 2013; and Sasquatch! music festival at the Gorge in Washington state, May 2013. Blu has also sponsored “vaping areas,” which show signs displaying the blu logo, in at least one Six Flags theme park in California. Six Flags is an amusement park that attracts thousands of visitors each year—many of which are families and young adults.<sup>12</sup>
- *Cartoons:* The website for blu has featured an animated cartoon pitchman named “Mr. Cool.” The cartoon, which included an animated video, is reminiscent of the notorious Joe Camel cartoon character that effectively marketed cigarettes to kids in the 1990s. (See Exhibit E.)

#### **Lorillard’s Age Verification for Access to Its E-Cigarette Website is Superficial**

Lorillard prides itself on its two-step age screening process for the blu website [www.blucigs.com](http://www.blucigs.com). A visit to the website, however, quickly shows that the age verification is superficial and inadequate to prevent youth access.

To access the blu website, an individual only needs to click on an icon that states “18+ (ENTER).” No validation of age is required. The individual is then directed to the full blu website, which includes information on e-cigarettes, a store, customer reviews, a support center, and more. This is a stark contrast to the age verification required to access Lorillard’s website for Newport, its leading brand of cigarettes. Accessing the Newport website is a multi-stage process that first requires individuals to enter their date of birth. Individuals are then directed to a second page where they must enter their full name, address, driver’s license number, and the last four digits of their social security number. Only after this information and the individual’s age are verified are they able to enter the website. (See Exhibit F.)

Having set up a more rigorous age verification system for its leading cigarette brand, Lorillard clearly has the knowledge and experience to set up a more advanced screening process for its e-cigarette brand. It has not, however; and the com-

<sup>9</sup> 2013 Florida Youth Tobacco Survey.

<sup>10</sup> GK Mediamark Research & Intelligence. Youth readership is 2,002,000 for *ESPN The Magazine*, 1,289,000 for *Rolling Stone*, and 1,727,000 for *Sports Illustrated*.

<sup>11</sup> National Cancer Institute. *The Role of the Media in Promoting and Reducing Tobacco Use*. Tobacco Control Monograph No. 19. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, June 2008.

<sup>12</sup> Americans for Nonsmokers’ Rights. “Do you think Blu e-cigarettes should be promoted at Six Flags?” [http://anr.no-smoke.org/site/MessageViewer?em\\_id=29281.0](http://anr.no-smoke.org/site/MessageViewer?em_id=29281.0).

pany offers no explanation for why the age verification processes differ. As a result, youth can be introduced to blu e-cigarettes just as easily as any adult.

Lorillard states that a second screening process takes place before an individual is allowed to purchase a product from the blu website. As before, however, this system lacks the rigor needed to effectively prevent youth from completing a purchase. Individuals need only enter a name, birthdate, and credit card information—information that could easily be taken from an older individual. A driver's license and social security number are not required for age verification.

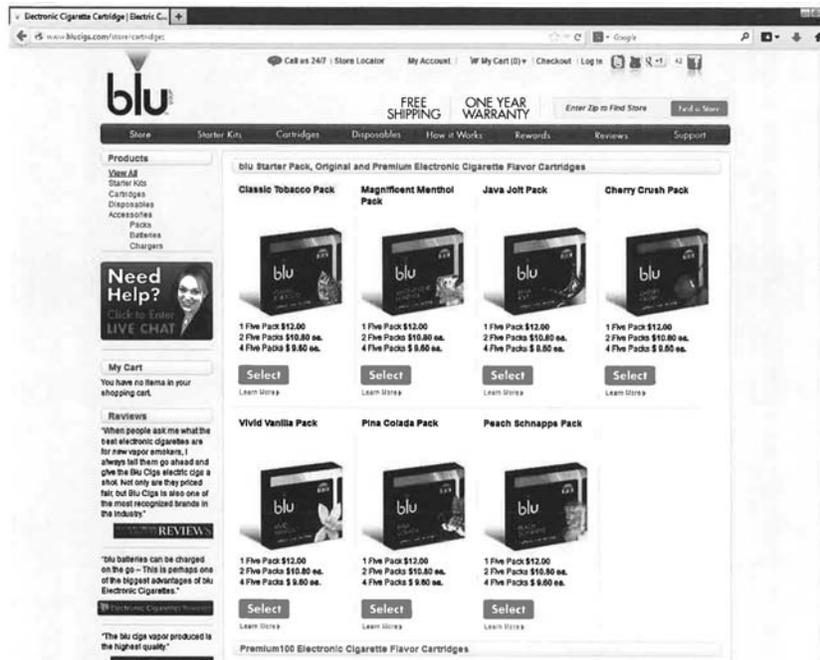
Lorillard claims to be a responsible e-cigarette manufacturer and implies that it is part of the solution for reducing tobacco-related harms. Its actions, however, show that it still is part of the problem. The strategies used to market blu e-cigarettes are the same irresponsible marketing strategies used by tobacco companies to market cigarettes to kids.

I urge the FDA to move quickly to regulate e-cigarettes and ensure that tobacco companies, like Lorillard, do not continue to market their addictive products to another generation of kids.

Sincerely,

MATTHEW L. MYERS,  
*President,*  
 Campaign for Tobacco-Free Kids.

Exhibit A: Screenshot of blu eCigs Website, November 1, 2013



**Exhibit B: Magazine Ads in Magazines with High Youth Readership**

*Magazine Ad Found In:*

*Rolling Stone:* April 25, 2013; May 23, 2013; June 20, 2013; July 4–18, 2013

*Car and Driver:* June 2013; July 2013

*Men's Journal:* June 2013; July 2013; August 2013

*Esquire:* June 2013

*Field and Stream:* June 2013; July 2013

*Playboy:* June 2013; July/August 2013

*Popular Mechanics:* June 2013; July/August 2013

**TAKE BACK  
YOUR FREEDOM**

with blu eCigs®, the smart alternative to cigarettes.

- Smoke Virtually Anywhere
- No Tobacco Smoke, Only Vapor
- Flavors Made in the U.S.A.

**blu™** electronic cigarettes are now available  
in retail stores nationwide.

Visit us at [blucigs.com/store-locator](http://blucigs.com/store-locator)

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**blu**

Source: Trinkets & Trash, [www.trinketsandtrash.org](http://www.trinketsandtrash.org)

Magazine Ad Found In:

Rolling Stone—May 2012

Filthy. Stinking. Rich.

blu ELECTRONIC CIGARETTE

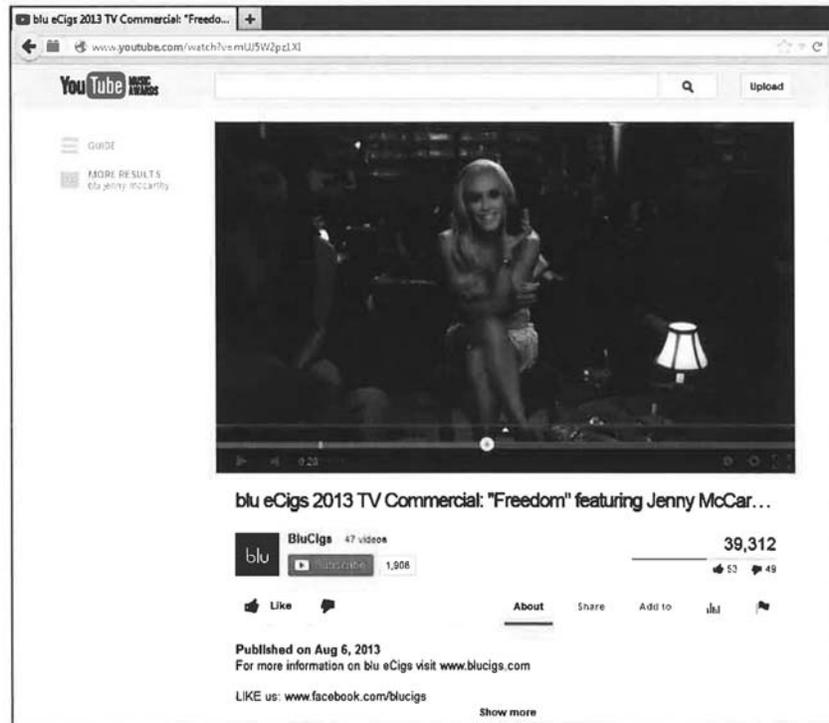
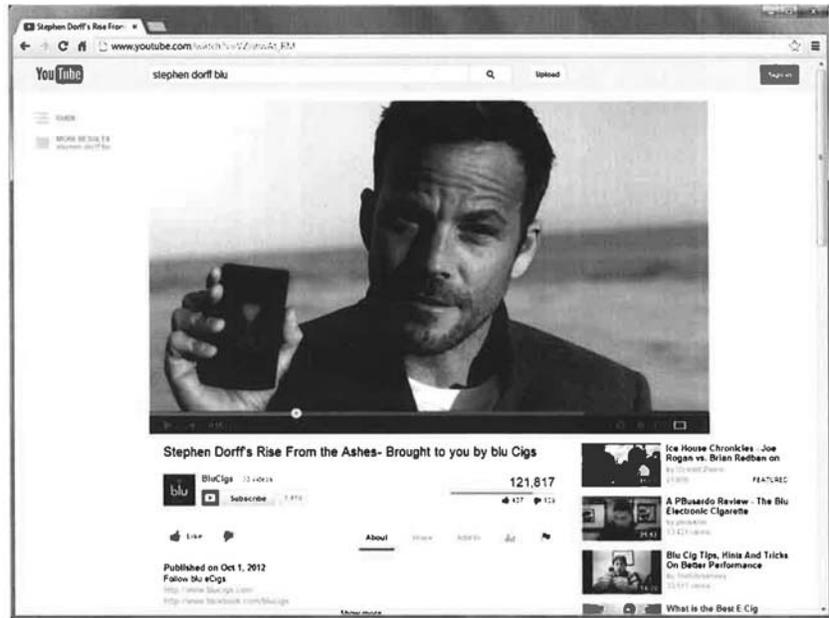
With no ash, no odor, and an unmistakably rich taste, blu is everything you enjoy about smoking without the things you hate. You control when and where you want to smoke. Take back your freedom with blu.

blucigs.com

18+ only. CALIFORNIA PROPOSITION 65 Warning: This product contains nicotine, a chemical known to the state of California to cause birth defects or other reproductive harm.

Source: Trinkets & Trash, [www.trinketsandtrash.org](http://www.trinketsandtrash.org)

Exhibit C: Screenshots of blu TV Advertisements on YouTube



**Exhibit D: Sports, Music, and Other Events Sponsorships**



blu IndyCar sponsorship



blu sponsorship of Bonnaroo Music and Arts Festival

**Exhibit E: Screenshot of “Mr. Cool” Cartoon on blu eCigs Website**



Exhibit F: Screenshots of blu eCigs and Newport Age Verification



The CHAIRMAN. Thank you, sir.

And now, Mr. Jason Healey is President of Lorillard subsidiary “blu E-cigs,” the market leader for sales and marketing in the e-cigarette industry.

We welcome you, sir.

**STATEMENT OF JASON HEALY, FOUNDER AND PRESIDENT,  
BLU ECIGS, A SUBSIDIARY OF LORILLARD**

Mr. HEALEY. Chairman Rockefeller, Ranking Member Thune, and members of the Committee, I am Jason Healey, founder and President of blu eCigs. It is a privilege to come here today to speak about a new product that has tremendous potential to reduce tobacco-related harm and disease and hopefully play a role in eliminating traditional cigarettes.

Back in 2008, I tried my first electronic cigarette. As a smoker, I saw tremendous opportunity for myself and other smokers. I immediately saw that this innovative product could provide an alternative to smokers who enjoy smoking or who struggle to quit like myself but don’t want the negative effects of traditional cigarettes on their health. I became convinced that e-cigs are just as much a disruptive force in tobacco as digital cameras once were to the film industry.

Today, every time I use an e-cig instead of a combustible cigarette, it is a good decision. I am not alone in seeing the potential. Public health experts have long considered harm reduction an effective approach to the reduction of risk caused by various behaviors. Harm reduction policies applied to tobacco will make great progress because we desperately need an alternative policy that complements prevention and cessation. Different types of nicotine occupy different points along what FDA calls a continuum of risk. Some activities carry less risk than others. Lacking combustion, e-cigs fall dramatically lower on this continuum compared to traditional cigarettes.

That is only logical because traditional cigarettes are very different. As one example of their significant difference, a recent study by our researchers found that harmful constituents present in cigarette smoke were at undetectable levels in the vapor of blue e-cigs, and similar to that found in Rumea. Our findings are consistent with other third-party research. I’ve included a summary of this analysis in my submission.

The CHAIRMAN. Sir, could you just say that last sentence once again, please?

Mr. HEALEY. Our finding—I’m sorry. To the harmful constituents?

The CHAIRMAN. Yes.

Mr. HEALEY. Our study by our researchers found that harmful constituents present in cigarette smoke were at undetectable levels in the vapor of blu e-cigs and similar to that found in Rumea.

The CHAIRMAN. Thank you.

Mr. HEALEY. We support science-based FDA regulation of e-cigs. And we are committed to working with the FDA manufacturing standards to ensure safety; age of purchase to ensure this is an adult-only product; content and nicotine labeling to ensure the consumers informed are supported by responsible manufacturers like

blu. We are encouraged that FDA's preamble to the proposed regulations seems to acknowledge that regulation should be proportional to harm and a one-size-fits-all approach is not appropriate.

We agree with Mitch Zeller, FDA's Director of Center for Tobacco Products when he said "We have to have an open mind on the potential for these emerging technologies to benefit public health."

blu, however, has not waited for FDA's action to address youth access. We have actively advocated for and supported state legislation to prevent minors from purchasing electronic cigarettes and we require third-party age verification for online sales.

blu began as a small entrepreneurial company, marketing a product with an emerging market with a challenge of introducing a product that did not effectively exist in the U.S. With the help of our parent company, we adopted strict and responsible marketing restrictions that reflect a clear and focus on adult smokers while also substantially reducing youth exposure to blu ads and promotions.

Our voluntary restrictions such as limiting ad placement to media and events where the target audience is at least 85 percent adult match or exceed restrictions adopted by comparable adult consumer product companies. As an industry leader, we believe these marketing restrictions demonstrate responsibility.

To reiterate, our marketing focus is to communicate to adult smokers that e-cigs are a viable alternative to cigarettes. We previously provided you with an explanation of the voluntary marketing restrictions that we have adopted. We have included this explanation in our submission that I provided to the Committee.

E-cigs have a tremendous untapped potential to positively change the lives of adult smokers of traditional cigarettes. Reaching this ambitious goal requires a new way of thinking and involves compelling marketing to normalize this behavior, and, as a result, de-normalize smoking. So adult smokers know it is a viable alternative worth their trial.

Further, we believe that using a variety of flavors is critical to keeping adult smokers who have switched to e-cigs from returning to more harmful combustible cigarettes. E-cigs are likely the most significant tobacco harm reduction product ever. Making less harmful products available as soon as possible should be a top priority.

Thank you.

[The prepared statement of Mr. Healy follows:]

PREPARED STATEMENT OF JASON HEALY, FOUNDER AND PRESIDENT, BLU eCIGS

Chairman Rockefeller, Ranking Member Thune and members of the Senate Commerce Committee, I am Jason Healy, founder and President of blu eCigs.

It is a privilege to come here today to speak about a new product that has tremendous potential to reduce tobacco-related harm and disease, and hopefully play a role in eliminating traditional cigarettes.

Back in 2008 I tried my first electronic cigarette. As a smoker I saw tremendous opportunity for myself and other smokers. I immediately saw that this innovative product could provide an alternative to smokers who enjoy smoking or who struggle to quit, like myself, but don't want the negative effects of traditional cigarettes on their health.

I became convinced that e-cigs are just as much a disruptive force in tobacco as digital cameras once were to the film industry. Today, every time I use an e-cig instead of a combustible cigarette, it is a good decision.

I am not alone in seeing the potential. Public health experts have long considered harm reduction an effective approach to the reduction of risks caused by various be-

haviors. Harm reduction policies applied to tobacco will make great progress because we desperately need an alternative policy that complements prevention and cessation.

Different types of nicotine use occupy different points along what FDA calls a continuum of risk. Some activities carry less risk than others. Lacking combustion, e-cigs fall dramatically lower on this continuum compared to traditional cigarettes.

That is only logical because traditional cigarettes are very different.

As one example of their significant difference, a recent study by our researchers found that harmful constituents present in cigarette smoke were at or near non-detectable levels in the vapor of blu e-cigs—and similar to that found in room air. Our findings are consistent with other third party research. I have included a summary of this analysis in my submission.

We support science-based FDA regulation of e-cigs, and we are committed to working with the FDA. Manufacturing standards to ensure safety, age-of-purchase to ensure this is an adult-only product, content and nicotine labeling to ensure the consumer is informed are supported by responsible manufacturers like blu.

We are encouraged that FDA's preamble to the proposed regulations seems to acknowledge that regulation should be proportional to harm and a one size fits all approach is not appropriate. We agree with Mitch Zeller, FDA's director of the Center for Tobacco Products, when he said, "We have to have an open mind on the potential for these emerging technologies to benefit public health."

blu, however, has not waited for FDA action to address youth access. We have actively advocated for and supported state legislation to prevent minors from purchasing electronic cigarettes and we require third-party age verification for on-line sales.

blu began as a small entrepreneurial company, marketing a product in an emerging market with a challenge of introducing a product that did not effectively exist in the U.S. With the help of our parent company, we adopted strict and responsible marketing restrictions that reflect a clear focus on adult smokers while also substantially reducing youth exposure to blu ads and promotions. Our voluntary restrictions, such as limiting ad placement to media and events where the target audience is at least 85 percent adult, match or exceed restrictions adopted by comparable adult consumer product companies. As an industry leader we believe these marketing restrictions demonstrate responsibility.

To reiterate, our marketing focus is to communicate to adult smokers that e-cigs are a viable alternative to cigarettes. We previously provided you with an explanation of the voluntary marketing restrictions that we adopted. We have included this explanation in the submission I have provided to the Committee.

E-cigs have a tremendous untapped potential to positively change the lives of adult smokers of traditional cigarettes. Reaching this ambitious goal requires a new way of thinking and involves compelling marketing to normalize this behavior, and as a result to denormalize smoking, so adult smokers know it is a viable alternative worth their trial. Further, we believe that using a variety of flavors is critical to keeping adult smokers who have switched to e-cigs from returning to more harmful combustible cigarettes.

E-cigs are likely the most significant tobacco harm reduction product ever. Making less harmful products available as soon as possible should be a top priority.

Thank you.

The CHAIRMAN. Thank you very much, Mr. Healey.

And now, Mr. Craig Weiss who is the President and CEO of NJOY electronic cigarettes; the second largest presence in the e-cigarette market.

**STATEMENT OF CRAIG WEISS, PRESIDENT AND CEO, NJOY**

Mr. WEISS. Members of the Committee and Mr. Chairman thank you very much.

My name is Craig Weiss and I am the President and CEO of NJOY. NJOY is an independent electronic cigarette company with no affiliation to the tobacco industry. We are proud to state that our corporate mission is to obsolete the tobacco cigarette and the death and disease that it has left in its wake.

I would like to focus on what I believe unites us and our company with the members of this committee, with the FDA Center for

Tobacco Products and with dedicated women and men in the tobacco control movement and public health. We look forward to a day when combustion cigarettes are no longer part of the American landscape. We are appalled at the toll of the tobacco epidemic has taken and continues to take each year on this country including 480,000 adult-Americans dying prematurely each year from tobacco-related illness.

The evidence clearly indicates that new approaches will be required to obsolete the combustion cigarette. Electronic Nicotine Delivery Systems, or ENDS, hold the potential to play a critical role. ENDS give smokers who either cannot or will not quit a positive alternative. They provide smokers with the nicotine that they are addicted to and crave without the combustion of tobacco. And as stated by the 2014 Surgeon General's report, "The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products. Rapid elimination of their use will dramatically reduce this burden."

We understand the great suspicion caused by the 2012 entry to the marketplace of the first of three major American cigarette companies. Well, major tobacco companies have now entered the category as cigarette sales fall, they did not create this industry and, most companies in the industry do not sell combustion products.

NJOY, which was established more than 5 years before the first major American tobacco company purchased an electronic cigarette company, is independent of the tobacco industry and has absolutely no incentive to promote combustion cigarette use among adults or youth.

ENDS are increasingly displacing cigarettes and their use is overwhelmingly by adult smokers. Reports from a CDC survey that experimentation of e-cigarettes among youth has risen should be taken seriously. However, the early fears that electronic cigarettes would entice young people to initiate with these products and then migrate to combustion products appear to be unsupported by the data at this point.

To be clear, no minor should be using a nicotine containing product of any kind. The maximum public health benefit will be achieved by mitigating risks to youth without constraining the ability for e-cigarettes to effectively compete with combustion cigarettes among adult smokers. Bans on sales to minors which we were among the first to support, are essential. We have long supported FDA regulation of this category and the FDA's issuance of proposed regulations is a critical milestone.

Cigarette-style advertising restrictions were not part of the FDA's proposed regulations. Subjecting electronic cigarettes to combustion cigarette-style advertising restrictions will only erect unnecessary barriers to effect a promotion of these products to adult smokers. Smokers are not going to purchase a smoking alternative that they're not aware of. It is important to realize that in the event that ENDS face the same advertising restrictions of combustion cigarettes, the big winner will be Big Tobacco who get to maintain their stranglehold on the more than 40 million Americans who smoke.

Still, even responsible television and other advertising should be delivered in a manner that is consistent with assertion that it is intended for adult smokers rather than for kids. NJOY's television campaign "Friends Don't Let Friends Smoke" is a clear illustration of this principle and we need more rather than less of this kind of advertising.

Analyzing information collected for its May 2014 report on e-cigarette advertising that Chairman Rockefeller referenced in his opening remarks, the American Legacy Foundation noted, "This data suggests that the marketing of NJOY is more focused on reaching an adult audience."

According to the Surgeon General, nearly 6 million of today's children will adopt smoking, grow up, and die prematurely from cigarette-caused disease if present trends continue. The best thing we can do for the health of all of our children is to ensure that they grow up in a world in which neither their parents nor any of their adult role models are smoking combustion cigarettes. Providing smokers who cannot or will not quit with a positive alternative may be the long sought solution to a massive public health problem that has cost millions of lives and more and more members of public health here and abroad are beginning to make their voices heard in support of this technology.

We need to approach regulation of this category in a manner that is guided by science rather than emotion or suspicion. There is too much at stake to do it any other way.

NJOY looks forward to working with the Committee to achieve the goal of obsoleting combustion cigarettes.

Thank you.

[The prepared statement of Mr. Weiss follows:]

PREPARED STATEMENT OF CRAIG WEISS, PRESIDENT AND CEO, NJOY

Members of the Committee.

My name is Craig Weiss, and I am the President and CEO of NJOY. NJOY is an independent electronic cigarette company with no affiliation with the tobacco industry. We are proud to state that our corporate mission is to obsolete the tobacco cigarette—and the death and disease that it has left in its wake. We want to see the combustion cigarette go the way of the rotary telephone and the horse-drawn carriage and we believe that technology and innovation are making this possible.

In my testimony today, I would like to focus on what I believe unites our company with the members of this Committee, the FDA's Center for Tobacco Products, and with dedicated women and men in the tobacco control movement and public health throughout the country.

We look forward to a day when combustion cigarettes are no longer part of the American landscape. We are appalled at the toll that the tobacco epidemic has taken and continues to take each year on this country—including 480,000 adult Americans dying prematurely each year from tobacco-related illness—or almost one adult each minute of every day. As Acting Surgeon General Lushniak stated during the presentation of the most recent Surgeon General's Report on smoking—"Enough is enough."

While the adult smoking rate has fallen from a high of over 40 percent to just under 20 percent and the teen smoking rate to a record low of 15.7 percent—the death toll from combustion cigarettes shows no signs of abating in this country or worldwide. The World Health Organization predicts one billion premature deaths from smoking in this century, and almost one American every minute has their life cut short because of combustion cigarettes.

The evidence clearly indicates that new approaches will be required to obsolete the combustion cigarette. Electronic nicotine delivery systems ("ENDS"), developed by entrepreneurs willing to take risks and break new ground, hold the potential to play a critical role. ENDS give smokers who either cannot or will not quit a positive

alternative to combustion smoking. They provide smokers with the nicotine that they are addicted to and crave without the combustion of tobacco. As stated by the 2014 Surgeon General's Report: "The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden."

Since at least 1995, influential members of the public health community have widely discussed a strategy of tobacco harm minimization, based on the availability of nicotine-containing, non-combustion products, to play a critical role in ending the tobacco epidemic. ENDS represent a potentially transformative, disruptive technology that threatens large and privileged incumbents.

We understand the grave suspicion caused by the 2012 entry to the marketplace of the first of the three major American cigarette companies. However, it is wrong to believe that ENDS are part of a grand plan by Big Tobacco to lure new smokers. While major tobacco companies have now entered the category as cigarette sales fall, they did not create this industry and most companies in this industry do not sell combustion products. Companies such as NJOY—which was established more than five years before the first major American tobacco company purchased an electronic cigarette company—are independent of the tobacco industry and have absolutely no incentive to promote combustion cigarette use, among adults, or youth.

ENDS are increasingly displacing cigarettes and their use is overwhelmingly by adult smokers. Reports from a CDC survey that experimentation of e-cigarettes among youth has risen should be taken seriously, yet seen in full context. Early fears that electronic cigarettes would entice young people to initiate with these products and then migrate to combustion products appear unsupported by the data to this point, with the rise in electronic cigarette popularity coinciding with a continued and indeed historic decline in teen smoking.

To be clear—no minor should be using a nicotine-containing product of any kind. The maximum public health benefit will be achieved by mitigating risks to youth without constraining the ability for e-cigarettes to effectively compete with combustion cigarettes among adult smokers. Bans on sales to minors, which we were among the first to support, are essential. As I will discuss in a moment, cigarette-style restrictions on advertising could inflict an enormous toll by obstructing the migration of current smokers to ENDS products.

We have long supported FDA regulation of this category, having first proposed the legal theory under which these products could be regulated under the *Family Smoking Prevention and Tobacco Control Act of 2009*, and we believe that FDA's issuance of proposed regulations is a critical milestone. Cigarette-style advertising restrictions were not part of FDA's proposed regulations nor should they have been. Subjecting electronic cigarettes to combustion cigarette-style advertising restrictions would only erect unnecessary barriers to effective promotion of these products to adult smokers. Smokers are not going to purchase a smoking alternative that they are not aware of, and advertising is needed to educate adult smokers of this alternative. It is important to realize that in the event that ENDS face the same advertising restrictions as combustion cigarettes, the big winner will be Big Tobacco, who get to maintain their stranglehold on the more than 40 million Americans who smoke.

Still, even responsible television and other advertising should be delivered in a manner that is consistent with the assertion that it is intended for adult smokers rather than for kids. NJOY's television campaign—"Friends Don't Let Friends Smoke"—is a clear illustration of this principle, and we need more rather than less of this kind of advertising. Analyzing information collected for its May 2014 report on e-cigarette advertising, the American Legacy Foundation noted, "This data suggests that the marketing strategy of NJOY is more focused on reaching an adult audience."

Paradoxically, children could be the biggest losers from an effort—in their name—to restrict e-cigarette advertising. According to the Surgeon General, nearly six million of today's children will adopt smoking, grow up, and die prematurely from cigarette-caused disease if present trends continue. The best thing we can do for the health of all of our children—and I am the proud father of two beautiful young kids below the age of 10—is to ensure that they grow up in a world in which neither their parents nor any of their other adult role models are smoking combustion cigarettes.

The balance will not always be a simple one and please be assured that, as a responsible company, we are committed to doing everything in our power to try to get it right. Providing smokers who cannot or will not quit with a positive alternative may be the long-sought solution to an intractable public health problem that has cost millions of lives—and more and more members of public health here and

abroad are beginning to make their voices heard in support of this technology. We need to approach regulation of this category with our eye on the prize and in a manner that is guided by science rather than emotion or suspicion. There is too much at stake to do it any other way. NJOY looks forward to working with the Committee to achieve the goal of obsoleting combustion cigarettes.

The CHAIRMAN. Thank you, Mr. Weiss.  
And finally, Mr. Scott Ballin.  
Did I get that right?

**STATEMENT OF SCOTT D. BALLIN, JD,  
HEALTH POLICY CONSULTANT**

Mr. BALLIN. Ballin.

The CHAIRMAN. I apologize.

Mr. BALLIN. Close enough.

The CHAIRMAN. I was betting on Ballin.

Mr. BALLIN. And happy birthday, sir.

The CHAIRMAN. Mr. Scott Ballin is a tobacco and health policy consult.

Mr. BALLIN. Yes.

Mr. Chairman and members of the Committee, thank you for the opportunity to be heard. I've spent much of my professional career dedicated to working in the public health arena and, in particular, tobacco and nicotine area. I worked for the Heart Association for many years, the Coalition on Smoking and Health. So I've been around a long time. So I also feel the age.

I come here today to give you my thoughts on issues being raised in this hearing, as well as on related issues. And some of those have come up here on what is a very dynamic, emotionally charged, and rapidly changing environment. This includes the broad topic of how all tobacco, nicotine and other products should be regulated, including their advertising and marketing.

I and many others, including the Director of the FDA Center for Tobacco Products, believe that we are in a new era; a sort of evolutionary next stage looking to develop a more comprehensive rational and workable approach to the regulation of all tobacco and nicotine products. This next stage could potentially be as significant as our acquiring of FDA oversight over tobacco just a few years ago. It entails how best to regulate a growing spectrum of products including e-cigarettes that holds significant promise for phasing out or one day virtually eliminating the deadly combustible cigarettes, but it's got to be done right.

It entails accepting and using what is commonly referred to as the continuum of risk today, which would regulate products based on their risks, their relative risks, and their intended uses. Gone are the days where we can conveniently say that all tobacco products are equally harmful. FDA oversight has changed the equation. Science and technology and innovation have changed the equation. New entrants into the marketplace, have changed the equation and consumers have changed the equation.

While there are many issues and sub-issues needing to be addressed in this new era two general areas of focus come to mind when it comes to reducing the harms caused by the use of tobacco. First, we need to be sure that no one, no one, under the age of 18 should be able to purchase any tobacco or nicotine product and that

we do everything feasible to prevent the initiation possession and use of any tobacco and nicotine product by anyone under the age of 18. This includes advertising and marketing that intentionally or unintentionally appeals to children and adolescents and it includes a discussion about what restrictions should be placed on flavorings. It is generally agreed that if we can prevent youth initiation we are a long way to advancing our public health objectives.

Second, we need to ensure that the approximately 40 million smokers in this country are provided with consumer acceptable regulated alternatives to the deadly toxic cigarette. That's what is killing people in this country. And someone noted earlier, Professor Mike Russell said many years ago, "People smoke for the nicotine and they die from the tar;" which, in many respects, is what this discussion is all about today.

To do this effectively we do need regulations that recognize that there are distinct differences in risk and relative risk between these products. One size does not fit all. We should also be encouraging better and more focused research in both the public and private sectors encouraging innovation, providing incentives to develop science-based lower-risk products and encouraging competition rather than stifling it.

In this rapidly changing environment, it's going to be essential that we approach the discussions of these issues in a more civil manner. And that is actually happening at this table today in many respects and I appreciate your leadership, Mr. Chairman.

There are numerous stakeholders involved who have seemingly differing views. I believe there's a lot more in common ground than people think. The Institute for Environmental Negotiation at the University of Virginia has been in the forefront in holding a series of safe haven tobacco dialogues where individuals can discuss issues in a non-adversarial manner. The first of the dialogues dating back to the 1990s, involved the public health community and tobacco growers which actually led to policy changes in this body and in the House that led to the enactment of the Tobacco Control Act and the tobacco buyout. That was monumental and many people said it could not be done.

The last three years have been focused on harm reduction issues and result in the set of core principles that were developed. Additional safe haven dialogues are being planned and we are going to try and expand those discussions to include a broader number of people.

FDA's proposed deeming regulations is also a place to start where stakeholders and other interested parties can make their views heard. While some disagree with the specifics of the proposal, I believe that FDA is also looking for new ideas and approaches. The door is open and I think that the fact that they haven't covered issues related marketing and advertising e-cigarettes allows that discussion to start taking place in the agency as well.

Mr. Chairman and members of this committee, there is a balance that needs to be achieved, which in my view can be a win-win for public health. We can deal with the issue of youth initiation of all tobacco and nicotine products including the impact of advertising and marketing, as well as helping millions of addicted adult smokers.

While we are making some progress, it is not enough. Clearly, not enough and that has been stated in this hearing as well. New approaches are needed as Dr. Ken Warner just told *Time* magazine a few days ago. And I agree with him. We need to think outside the box on some of these things.

Within the next 10 years, I would like to see the number of children and youth initiating and using cigarettes cut by 75 percent. The numbers of adult smokers cut at least in half; a major shift away from the manufacturing of deadly, toxic cigarettes to the development, manufacturing, and use of significantly lower risk, science-based regulated products.

I believe that, given the proper regulatory tools at the FDA coupled with incentives, innovation, research, marketplace competition, and cooperation amongst various stakeholders, we can do it. And we can save a lot of lives in the process.

Thank you.

[The prepared statement of Mr. Ballin follows:]

PREPARED STATEMENT OF SCOTT D. BALLIN, JD, HEALTH POLICY CONSULTANT

“At first people refuse to believe that a strange new thing can be done, then they begin to hope it can be done, then they see it can be done—then it is done and all the world wonders why it was not done centuries ago.”—*A Secret Garden* Francis Hodgson Burnett

Mr. Chairman and Members of the Committee, I want to thank you for this opportunity to appear before this Committee. I have spent most of my professional career dedicated to working in the public health arena and in particular on tobacco and nicotine issues. FDA regulatory oversight was something I took on at a time when some said I was on a “fool’s errand”.

In those early years it was pleasure and honor to work with a number of members of the House and Senate on not just that issue but others as well. One of the early champions in those efforts was Senator Durbin who was anticipated to be your lead-off witness. Several members of this Committee including Senators Markey and Blumenthal have also been in the forefront on a number of tobacco related issues.

Today we are talking about another potential major monumental shift, possibly as significant as acquiring FDA oversight of tobacco. It entails how best to regulate a growing spectrum of tobacco, nicotine and alternative lower risk products, including e-cigarettes, that hold promise for significantly reducing, or one day virtually eliminating the use of the deadly combustible cigarette.

I come here today representing no one but rather to give you my 35 plus years of experience and thoughts on how all stakeholders might consider “moving forward”. I include on that list, policy makers, regulators, public health advocates, researchers, manufacturers, healthcare practitioners, consumers, and the general public.

The subject of this hearing raises some important questions that need addressing. I hope that *both* the majority and minority will approach the focus of the subject of this hearing as part of a broader and more comprehensive discussion which encompasses *the need for the regulation of all tobacco, nicotine and alternative products—regulation which should be set based on the risks, relative risks and intended uses of those products.*

**We are in a “New Era” of Tobacco, Nicotine and Alternative Products Regulation**

We are in what I and others have called a “New Era” and what FDA’s Center for Tobacco Products Director Zeller has called a “New Beginning”, an era that demands that we look at more effective and appropriate ways for regulating a growing spectrum of tobacco and nicotine products which have very diverse “risk profiles”. Gone are the days when we could make the simple statement that all tobacco products were equally harmful. FDA oversight has changed the equation. Science has changed the equation. Innovation and technology have changed the equation. New entrants into the marketplace have changed the equation and consumers have changed the equation.

The Center for Tobacco Products (CTP) has had and will continue to have many mountains to climb in not only carrying out the many mandates that Congress imposed on it but more importantly in dealing with the challenges for shaping new policy over the next 5–10 years.

In 1976 Professor Michael Russell wrote, “People smoke for nicotine and die from the tar”. That statement, made decades ago, is what this is all about today. This “New Era” is therefore about the development and implementation of a *comprehensive and workable tobacco, nicotine and alternative products policy* that will require the active involvement of all stakeholders. It is about saving lives. The tobacco nicotine and alternative products environment is at a crossroads.

The swiftness with which e-cigarettes have gained popularity has caught many off guard including the public health community, tobacco control advocates, researchers, policy makers, regulators, the public, and even manufacturers. Today, it is estimated that there are somewhere between 5,000–10,000 e-cigarette/vaping manufacturers, companies and stores with a growing array of differing products. While I have long believed that there would be new categories and new products entering in the market, I like everyone else have been overwhelmed with what has happened. This presents both challenges and opportunities. We should not forget that the cigarette market in the U.S. is around \$85 billion. Most smokers want to quit and if we can provide those smokers with science-based, consumer acceptable lower risk products we could fundamentally alter the current marketplace and save hundreds of thousands of premature deaths.

I see and hear a great deal of emotional, adversarial (some of which is unproductive) discussions going on in and outside the public health community about the benefits and harms associated with e-cigarettes. Research studies are coming to very differing conclusions. Unfortunately but not unexpectedly, such research is often “cherry picked” for both lobbying and public relations impact.

#### **Regulation of All Tobacco, Nicotine and Alternative Products Should Be Based on the Risks, Relative Risks and Intended Uses of the Product**

In addition to recognizing the importance of developing a new comprehensive tobacco and nicotine policy, the FDA’s “deeming” proposal has also recognized the need to regulate products based on risks and relative risks—what is referred to as the “*continuum of risk*”. There are significant differences in the risks between products already in the market place as well as new innovative products being developed. This includes not only the categories of products such as the combustible cigarette on one end and nicotine replacement therapies (NRT) on the other, but other smoke-free tobacco products (snus, lozenges, inhalers etc.), e-cigarettes and an array of products within the various categories. As we accept and recognize this reality, we also will need more focused and in some ways better research being done that will have to come from both the public and private sectors including the manufacturers of these products, who will be required to provide data and information to the FDA to back up their products with sound scientific evidence.

In terms of better understanding some of the various components at work with respect these broad-ranging significantly lower risk products (that includes e-cigarettes) and what will be needed to drive change, I use the following equation:

$$\text{REGULATION} + \text{Research and Science} + \text{Technology} + \text{Innovation} + \text{Incentives} \\ + \text{Competition} + \text{Consumer Acceptability} =$$

A means of advancing public health goals *and* changing the behaviors of those manufacturing and marketing tobacco, nicotine and alternative products.

(Side Comment: While seemingly out of context, I think that we may one day be having similar conversations about marijuana, an agriculturally based product; a drug that can be used in both combustible and non-combustible forms and which is used both recreationally as well as for medicinal purposes. Will/should it come under FDA’s authority and if so where and how?)

#### **The E-Cigarette Challenges and Opportunities—Critical Elements Needing to be Addressed**

1. *First and foremost, e-cigarettes should/must be regulated by the Food and Drug Administration with regulation being designed to advance public health goals.* This includes how they are manufactured, labeled, advertised and marketed. When the original statute was drafted the statute provided no real flexibility for considering other products. The statute, in spite of its historic importance was already outdated in many areas the day it was signed into law. FDA has been challenged with ‘defining’ nontraditional products often having to try and fit a square peg into a round hole. They tried initially to regulate e-cigarettes under the drug and device statutes but gave up on that approach after legal challenges, and have taken a path to regu-

lating them as tobacco products as long as no therapeutic claims are made. Enter the “deeming” regulations.

While tardy in being issued, the FDA’s “deeming proposal” has opened the door for the involvement of a broader spectrum of stakeholders and interests to submit their views and comments. Input and new ideas need to be heard and discussed if we are to move forward. It is obviously not a process that some believe is fast enough and many want “action now” particularly when it comes to concerns of children and adolescents. But FDA and all of us who have an interest in the subject of tobacco and nicotine regulation are on a “learning curve” being challenged to think differently and realizing that like it or not this is not the 1980s or 1990s. The e-cigarette issue is not black and white, one size does not fit all and we should be very cautious about *over-regulating* a product that many believe has the *potential* for playing an important role in reducing disease and death caused by the combustible cigarette—the primary product causing close to 3.5 million premature deaths globally and 480,000 premature deaths in the U.S.

Just as the disrupting technology advances of 100 hundred years ago in the form of “machine-made” cigarettes that are at the root of today’s smoking epidemic, today we are looking at disrupting technologies, that if implemented carefully, could help end that 100 years of cigarette-related disease and death. And people are talking about this possibility in ways that they did not just a couple years ago.

Here are a couple examples of recent statements, reports that can now be added to the numerous states that have been issued or made over the last several years.

A. *Letter to WHO Director General Margaret Chan from 53 Tobacco and Nicotine Specialists*

A few weeks ago (May 25) 53 tobacco and nicotine specialists sent a letter to World Health Organization Director General Margaret Chan asking that the WHO give serious consideration to incorporating tobacco harm reduction (which includes e-cigarettes) as part of its efforts to reduce disease and death caused by the use of tobacco. The opening two paragraphs of that letter state:

“We are writing in advance of important negotiations on tobacco policy later in the year at the FCTC Sixth Conference of Parties. The work of WHO and the FCTC remains vital in reducing the intolerable toll of cancer, cardiovascular disease and respiratory illnesses caused by tobacco use. As WHO has stated, up to one billion preventable tobacco related premature deaths are possible in the 21st Century. Such a toll of death, disease and misery demands that we are relentless in our search for all possible practical, ethical and lawful ways to reduce this burden.

It is with concern therefore that a critical strategy appears to have been overlooked or even purposely marginalized in preparation for FCTC COP-6. We refer to “tobacco harm reduction”—the idea that the 1.3 billion people who currently smoke could do much less harm to their health if they consumed nicotine in low-risk non-combustible form.”

B. *A recent report (June 2014) by Action on Smoking and Health (ASH) in the UK entitled: **Electronic Cigarettes (also known as vapourisers)***

Just released by Action on Smoking and Health in the UK is a report on electronic cigarettes where those in the UK are having conversations similar to those going on here in the U.S. While the entire document is worth reviewing, here is a brief excerpt on the concept of harm reduction.

Smoking in the largest preventable cause of premature mortality in the UK. The goal of tobacco harm reduction is to diminish the harm caused by tobacco products. While the ideal remains that people stop using tobacco completely and permanently, consensus currently supports a properly regulated harm reduction approach for those unable to do so. This is a frame work by which the harmful effects of smoking are reduced without requiring the elimination of a behavior that is not necessarily condoned. Such strategies have proved successful in the past, for example, within the contexts of needle exchange programmes, illicit drug use and the promotion of safer sex to prevent HIV infection.

(The entire report can found at: <http://www.ash.org.uk>)

C. *Position of LEGACY*

Last week (June 11, 2014) I attended the Ken Warner Lecture Series sponsored by Legacy—a one on one discussion between the Legacy’s President and CEO, Robin Kovel and FDA/CTP’s Director Mitch Zeller. I also picked up Legacy’s latest position statement on e-cigarettes—*E-CIGARETTE POLICY: THE FDA SHOULD PROMPTLY EXERCISE REGULATORY AUTHORITY OVER E-CIGARETTES*. In reading it

I have to say that I concur with much that was presented and believe they have done a very thoughtful job in approaching this very challenging and controversial subject. Here are a couple excerpts, but again I encourage everyone to take a look at this somewhat cautious but 'forward looking' statement in times of uncertainty.

"In the U.S., more than 43.8 million people smoked cigarette in 2011, and about half of lifelong smokers will die premature from their tobacco use. Legacy recognizes that, on an individual level, there is a continuum of risk across tobacco products with combustible products (*e.g.*, cigarettes, cigars, hookah) posing the most danger and Food and Drug Administration (FDA) approved nicotine replacement therapies (NRT's) posing the least harm. Harm reduction is a valuable public health strategy with the potential to reduce, although not eliminate, the preventable disease and death caused by tobacco. E-cigarettes may hold great promise in this regard. While they are not without risk, initial scientific evidence suggests that, for the individual smoker, they are likely less harmful than smoking cigarettes, and they likely have significant lower levels of known tobacco toxicants than combusted tobacco products. In addition, e-cigarettes may help some smokers quit. However, the existing evidence is insufficient to support any informed inference on net public health benefits versus harm at this time.

The impact on individuals is only part of the story. We must also consider e-cigarettes' impact on public health at a population level . . .

FDA must promptly exercise its statutory authority to regulate e-cigarettes and begin the process of carefully evaluating and resolving these literally life and death questions consistent with that authority. In addition, the Federal Trade Commission (FTC) should put a stop to the unsupported health claims currently being made about certain e-cigarette products that may mislead the public."

(To view the full statement and other related materials on e-cigarettes, go to: [www.LEGACYFORHEALTH.ORG](http://www.LEGACYFORHEALTH.ORG))

## 2. Concerns

One of the concerns being raised and which is the subject of today's hearing is what is happening or may be happening with respect to increased advertising and marketing that intentionally or unintentionally might have an impact on children and adolescents. What is appropriate and what is not, as we wait for FDA to issue its final deeming regulations? Once we have identified the potential abuses we then have to ask how those abuses can be curbed without negatively impacting on how these science-based lower risk products can be used to help cigarette smokers quit.

There are other concerns as well such the role that flavors *might* play in youth imitation, childproof packing of some items, and product safety issues in general. It will be imperative that as we move forward in our efforts to address those concerns we look for productive positive and non-adversarial ways of addressing them. On the issue of flavorings, any concerns about flavoring and youth initiation should be balanced with ensuring that significantly lower risk products such as e-cigarettes are consumer acceptable to the millions of smokers looking to quit. This obviously involves flavorings and palatability. Nicotine replacement therapies (NRT) have long been available in a wide variety of flavors ("fruit chill", "cherry", "lime", "mocha" etc.) and are marketed and promoted in variety of ways. Smokeless tobacco products also have flavoring allowances. Similar types of allowances could be made for e-cigarettes.

The experience that we encountered with the misleading and deceptive advertising and marketing practices of Big Tobacco should never forgotten but this is a very different environment and although we face similar challenges we can and must approach the issues differently especially since we now have a regulatory agency (FDA) in place to address these complex and challenging issues. Big Tobacco fought us at every turn including oversight and regulation and it is easy to see why so many of my colleagues remain entrenched in their views and resistant to new approaches. Today, like it or not tobacco, nicotine and alternative product manufacturers are considered stakeholders by the FDA in this new era and they will be obligated to comply with FDA's rules and regulations or face severe enforcement penalties.

Juxtaposed to what I laid out above with respect to the need for a more comprehensive, rational and workable tobacco and nicotine policy is the need, therefore, to look at some of the children and adolescent issues being raised.

Without giving Legacy too much attention, I suggest that their e-cigarette paper gives us some direction on issues related to youth initiation and raises issues that need to be addressed. The Durbin et al report, *Gateway to Addiction?* does the same,

as do background papers from other organizations—some who are appearing at this hearing.

Legacy’s position paper on e-cigarettes notes:

- *“Legacy believes that e-cigarettes should not be sold or marketed to youth. This includes enacting many of the marketing/advertising restrictions currently applicable to cigarettes, including age restrictions on sale, placement of the product in retail outlets, and restricting advertising that is directed towards youth. Regulators should carefully research the issue of whether advertising is re-glamorizing smoking in general and monitor the impact on youth uptake of e-cigarettes and combusted products.”*

As part of addressing these and other concerns, manufacturers should be encouraged and be willing to provide non-proprietary information to the FDA and to the public as the ‘deeming’ regulations are developed.

**Can those interested in the e-cigarette issue who are concerned about youth but who also recognize the role that harm reduction could play find common ground to accomplish both?**

A. My experience dating back to the 1990s indicates to me that we can and must. I have had the opportunity to be involved both as a participant and now as an advisor to ongoing efforts by the Institute for Environmental Negotiation (IEN) at the University of Virginia to foster “safe haven” professionally mediated dialogues on issues related to tobacco, nicotine, and alternative products harm reduction. The IEN had been instrumental in bringing the public health community and tobacco growers together that resulted in a series of Core Principles that included FDA regulatory oversight and the tobacco buyout—something some thought impossible. Today the IEN is carrying on those discussions and has issued a set of Core Principles that suggest a number of areas of focus that might successfully help move a tobacco, nicotine, and alternative products harm reduction strategy forward. In order to encourage and foster dialogue IEN employs a variation of the Chatham House Rule. The Core Principles are not intended to be “owned” by anyone but can be used “in toto” or in part by everyone. They are a form of guidance. The IEN hopes that more and more people who support the “concept” of tobacco, nicotine and alternative harm reduction will become more actively engaged.

These *Core Principles* include topics such as:

1. Definitions and Terminologies: Adapting to a Changing Environment
2. Regulatory Oversight
3. Research and Science
4. Innovation and Technology
5. Monitoring and Surveillance
6. Consumers and the General Public
7. Tobacco Agriculture
8. Engagement and Dialogue

(For a complete copy of the Core Principles (2013), go to the IEN website at: [www.virginia.edu/ien/tobacco](http://www.virginia.edu/ien/tobacco))

B. So where do I think there might be some general consensus on some general principles by a significant number of stakeholders?

1. That no one under the age of 18 (21) should be able to purchase *any* tobacco or nicotine containing product including e-cigarettes. This should include such things as (as are applied to some tobacco products already) age verification, face to face sales, restrictions on vending machines etc.
2. That *all* tobacco, nicotine, and alternative products are regulated by the FDA. FDA needs to move forward with the deeming regulations as expeditiously as possible but it needs to get it right. Regulations should be designed to advance public health objectives both for the individual and the population as a whole.
3. Advertising, marketing and sponsorships should be carefully scrutinized and restricted where such advertising attracts children and adolescents.
4. That the degree of regulation of products be determined by using the “continuum of risk” which would regulate products based on risks, relative risks and intended use.
5. That areas of regulation include but not be limited to sales and distribution, labeling, ingredient disclosure, product standards, advertising and marketing,

GMP's and the child proof packaging of all tobacco, nicotine and alternative products where appropriate.

6. That FDA in conjunction and with the cooperation of manufacturers, public health authorities, retailers, distributors and others needs to implement a *comprehensive monitoring and surveillance system that covers all tobacco, nicotine and alternative products. We need to know what is happening in the marketplace.*
7. That consumers of all tobacco and nicotine products be given truthful and non-misleading information about the risks and relative risks of products that includes not only warnings but other useful information about the growing spectrum of products;
8. That FDA (and where appropriate the FTC) use its enforcement authorities to take action against any manufacturer, retailer, wholesaler etc. who violates the law;
9. That if the use and possession of *any "nicotine" product* by adolescents is of such great public health concern (as many, including myself, clearly think it is)—that like alcohol and other areas where adolescents must bear some responsibility for their actions, we begin a *serious discussion* about expanding minimum age of sale restrictions to include the *use and possession* of any tobacco or nicotine product. Given that initiation is of such great concern, the time may be ripe for trying to prevent anyone under a certain age (18) from buying, possessing or using any tobacco or nicotine product.
10. That FDA, while focusing on the abuses of aggressive advertising targeted at youth, also begin considering how best to convey *truthful, complete and non-misleading information to the public about the risks, relative risks and intended uses* for all tobacco, nicotine and alternative and consider initiating a well-balanced public educational campaign. (It is my feeling that until and unless this happens, confusion will continue to reign in the marketplace and some companies will continue to skirt the fine line between what is appropriate advertising and marketing and what is not).
11. And last not but least that the "deeming" regulations should be considered the primary avenue for setting balanced, fair and effective standards for regulating all tobacco and nicotine products and that FDA should continue to encourage the active participation of all interested parties in submitting their comments.

**While the FDA deeming proposal is where we need to be focusing, are there things that can be done with respect to curtailing the advertising and marketing of e-cigarettes to children and adolescents as we await final regulatory outcomes?**

The simple answer is "yes" we can and should do more. But in doing so, we shouldn't be throwing out the baby with the bathwater and we need to not lose sight of the fact that our public health goals should be to *reduce disease and death* caused by tobacco use—the primary concern of which has been, is and should continue to be with the deadly toxic cigarette.

Here are some things to consider in keeping attention on this issue——

1. The public at large and consumers of tobacco and nicotine products need to be *truthfully and honestly educated* about the risks and relative risks of products in the marketplace, including e-cigarettes. This needs to come from all stakeholders. This includes information about what our policies should be with respect to children and adolescents but it goes much further. The time has come to do this in a serious manner and to abstain from what often becomes a 'media circus' that does little to nothing to advance the ball forward and that will only continue to confuse the public.
2. In the area of advertising and marketing FDA and the FTC should actively work together to monitor advertising, expeditiously taking action when appropriate and necessary.
3. E-cigarette manufacturers, either through the actions of individual companies or collectively, need to make it clear where they stand on a variety of issues not just to regulators but to policy makers and the public at large. As we wait for the deeming regulations to be issued, some sort of interim "code of conduct" might help in providing some accountability.
4. This Committee, as well as the Senate Health Education Labor and Pensions Committee, and your counterparts in the House need to play a leadership role and less of a reactionary role in helping to shape the necessary policies to carry

us forward. The time is ripe for our policy makers to come into the 21st century and recognize that this is indeed a “New Era”. Design the policy parameters but let the FDA do its job.

5. FDA needs to consider not just doing “listening” sessions but also be willing to sponsor/convene workshops and forums in order to keep the discussions on these important issues going and more visible as we await the final deeming regulations.

Mr. Chairman and members of the Committee I thank you for the opportunity to be here today to express my views and to suggest some ideas about how we can move forward in this rapidly changing environment. There is a *balance* that needs to be achieved and the only way we can achieve that balance is to keep the discussions going, our minds open, our willingness to listen and learn, and to remain focused on the goal of reducing disease and death from tobacco use.

My views have remained very consistent for many years. In August of 2011, I gave a key note presentation at the Food and Drug Administration concerning modified risk tobacco and nicotine products saying:

“The sale and marketing of *all* tobacco and nicotine products should (as recommended by the IOM report, *Clearing the Smoke*, be carefully monitored and if legitimate and serious issues are found, corrective actions should be taken by the FDA. Implementing a workable surveillance system for all products (not just MRTP’s) should be given a high priority. Since companies (tobacco, pharmaceutical, biotech, etc.) will be the ones that will be required to collect the data, it needs to be done in a collaborative way with the FDA in order to achieve maximum results.”

David Abrams, Professor of Health Behavior and Society at the Johns Hopkins Bloomberg School of Public Health has referred to this “balance” as it relates to e-cigarettes as the Goldilocks test. Regulation should not be too hot (that we prevent smokers from having access to consumer acceptable products) and yet it must not be too cold either (that would allow irresponsible manufacturers the opportunity to make claims and target children and adolescents). They need to be “just right”. As we pursue our public goals we must therefore be careful not to “throw the baby out with the bath water”.

Thank you.

The CHAIRMAN. Thank you, Mr. Ballin.

I almost don’t know where to begin.

Mr. Weiss, so I guess what you were saying is that you sort of had a corporate board meeting and you decided that the corporate purpose of your company would be to reduce cigarette smoking among adults and, therefore, you went to e-cigarettes as a way of so doing?

Mr. WEISS. Yes.

Our corporate mission is to obsolete the combustion cigarette.

The CHAIRMAN. So that would then lead necessarily to the conclusion that you don’t do any advertising in some of these magazines and TV, which had been discussed. You don’t advertise in areas that would appeal to youth to use e-cigarettes, because you wouldn’t need to do that because you have a different mission. It’s the adults that you’re working on. You’re not working on kids.

Mr. WEISS. That’s correct.

We’re only interested in adult smokers and—

The CHAIRMAN. So you don’t do any advertising?

Mr. WEISS.—we do advertising that’s targeted toward adult smokers.

The CHAIRMAN. And is that advertising that is aimed at adult smokers the kind that was discussed by Mr. Myers?

Mr. WEISS. He didn’t hold up any of NJOY’s ads and as I’ve mentioned, the American Legacy Foundation—

The CHAIRMAN. Well, come on. You understand what I'm saying. In other words, appealing to young people.

Mr. WEISS. I don't believe that our ads appeal to young people.

The CHAIRMAN. Well life is easy, isn't it, when you can just answer like that?

All right. You're on the record there.

This is to all the witnesses but not everybody has to answer. I'm worried, obviously, e-cigarette marketing reaching youth that appears to be the case. If people have figured out a way to actually be just trying to affect adults but get 9.5 million people who read advertisements and 14 million people who see advertisements about e-cigarettes, that's making an interesting discussion.

But, limiting cigarette marketing to youth has been central to the multi-decade effort to prevent young people from becoming addicted to smoking. And, it's well established that nicotine is the addictive ingredient in cigarettes.

So, Mr. Myers and Dr. Tanski, would you agree that a sustained and prolonged smoking prevention and tobacco control effort, there has been an encouraging decline of youth rates of cigarette smoking in this country?

Dr. TANSKI. You're absolutely correct.

There has been a wonderful decline in the rates of smoking. The data that just came out last week showed a low of 15.9 percent prevalence amongst our high school youth, which is the lowest rate in 22 years. So there have been great strides in reducing cigarette smoking among our youth.

The CHAIRMAN. OK, I get the drift.

Now, e-cigarette manufacturers say that their target audience is just adult smokers and that the other, the youth, don't figure in.

Senator Boxer, what gets me is this gets so to the integrity of corporate culture and what people will do when they're given the chance to make money. I'm sorry. That's so deeply embedded in me that's why I started out by saying I'm on edge emotionally on this whole hearing.

But by blanketing a wide variety of media with advertisements, aren't these companies also creating the risk of introducing a whole new generation of young people starting zero through five to the highly addictive substance called nicotine?

Mr. MYERS. Yes, sir.

That's exactly our fear. There is a whole generation of young people who have grown up since the Master Settlement Agreement and other restrictions who've never seen a TV ad glamorizing cigarettes, who have never seen the kind of advertising I showed you and I could have shown you dozens more of those ads as well. And we are deeply concerned that, while e-cigarette companies should be free to inform adult consumers, there are ways to do it that don't require them to put ads on the bikini bottoms of women in *Sports Illustrated*, sponsor rock concerts. I could show you YouTube's of central and provocative images. There is a way to communicate to adults.

The CHAIRMAN. I get your drift. I get your drift.

Now, the argument has been made that nicotine is what people get addicted to but tar is what kills them. I'm so stunned by that because of the one and the other are the same. In other words,

you'd have to prove that nicotine is sort of good for your health for a young person. How would they possibly saying they're getting addicted on nicotine but there not being tar present. It's good for them.

Mr. MYERS. There are two points. Nicotine is dangerous to young people, specifically, while their brains are being formed.

The CHAIRMAN. Right.

Mr. MYERS. So there is no such thing as the safe delivery of nicotine particularly in the uncontrolled levels and then these kinds of things that we've seen for a young person.

Through FDA regulation, we have shown that it is possible to deliver carefully titrated deliveries of nicotine to adults for at least periods of time, which going on in the current marketplace for e-cigarettes, however, is that nicotine is being delivered in uncontrolled levels with uncontrolled flavors and no quality control. And to say that that does not pose a potential risk is a misstatement.

Chapter five of the most recent Surgeon General's report focused entirely on the toxicity of nicotine. So it is a 100 percent true statement that nicotine isn't what causes cancer but nicotine is not a benign substance. That's why it has always been regulated by the FDA and why it needs to be regulated by the FDA in e-cigarettes to protect the public as well.

The CHAIRMAN. I thank you.

My time is up but I, with the indulgence of my distinguished Ranking Member, I just want to give Mr. Healey a chance to respond to what I'm positing.

Mr. HEALEY. Thank you, Mr. Chairman.

First, for myself, I, being a father besides a businessman, do not want my product in the hands of children. And it's something I think we take very, very seriously but, at the same time, we try not to lose sight of the big picture of the 41 million smokers like myself.

We also look and watch whether it, by our voluntary advertising restrictions, that we've put in place that we actually got out of the Tobacco Act. And we put those policies on ourselves and then we also look at who is buying. And when we look at who is buying blu, the average age is 51.1 years old. So we watch both ends of the equation, where we're showing it, but also what the results of what we're doing now because we have to be responsible for the results.

The CHAIRMAN. As I said, my time is up. And, I apologize to my Ranking Member.

Senator Thune.

Senator THUNE. Thank you, Mr. Chairman.

Mr. Myers, assuming that we all agree that children should not be able to purchase these products, what's your view on whether e-cigarettes have the potential to reduce harm if current adult smokers of combustible tobacco cigarettes switched to them?

Mr. MYERS. As I said, if properly regulated in terms of quantity of nicotine; how it's delivered; the manner of, and its delivered; and it's targeted to a current smoker who couldn't otherwise quit, with the levels of nicotine sufficiently so that they switched exclusively to e-cigarettes, I don't there's any doubt that there would be a reduction in our—

Senator THUNE. What's your, sort of, general view with regard to the science around e-cigarettes? Do you view it as settled?

Mr. MYERS. No.

The science is not settled and the science couldn't be settled because the product itself is changing. Unfortunately, we haven't had the kind of rigorous science for this that we'd require for any other product under the regulation of the FDA.

Our organization, I think all of the other public health groups, would welcome rigorous science so that if e-cigarettes have the potential to help millions of smokers quit, we do the kind of science so that we're sure that the product that we're selling to them will actually accomplish that goal.

In the absence of regulation, what we've seen is products with nicotine levels of enormously different levels; high enough to be of concern and, in some cases, so low that the fear is it just makes it too easy for kids to start because nicotine is harsh. And the last thing we want to do is have a perfect product for a kid to start as well as advertising.

So it is science that should drive the precautionary principle of protecting our kids in how we go about developing that science.

Senator THUNE. Thank you.

Mr. Ballin, there has been a lot of discussion about the benefits and harm of e-cigarettes, as you know. In your testimony, you agree with Mitch Zeller, the Director of FDA Center for Tobacco Products, who has recently said that "there's a continuum of risk for nicotine-containing products."

You also stated that any regulation of those products should be based on the relative risk and intended uses. Can you elaborate on how we can find the appropriate balance for e-cigarettes and what some of the key players can do to further the dialogue and scientific research?

Mr. BALLIN. Yes.

I think that, you know, what I'm hearing around this table is actually a common direction of what needs to be done. There needs to be more research. There's no question about it. It needs to be done by FDA internally, NIH, and other places coupled with universities and other academics. Also, industry has a responsibility.

I think there was a statement made by someone earlier that there has to be accountability of this industry. And I think that as the agency begins to regulate these products, and anybody wants to file an application with the agency, they're going to have to have the proof to back up whatever they're asking for the agency to approve a product or also allow a claim or anything else.

We need to head that in that direction, very quickly. I agree with a lot of what's been said at this table.

The other thing is I think we need an aggressive monitoring surveillance system. We talked about that many, many years, over the years, you know, in the public health community and at FDA. And I think that in order to find out what's going on in the marketplace, we need to be able to tap into the industry documents, if it's a proprietary information, FDA needs to do a better job of coordinating efforts to see what's happening out there so we can take the necessary steps to take action.

There are a lot of things that need to be done; there's no question about it. But I think collectively and responsibly, if it's done properly, we are going to be able to deal with some of the issues we've talked about today.

Throwing grenades at each other, I don't think it's going to be productive. And that's why, over the years, I've come to the conclusion that when people actually can sit down in a room without negotiating anything and have a civil conversation off-the-wall, you know, off-the-record conversation, progress can be made. It may not be, but until you start talking you're never going to find out. And I will say that again, for me, this hearing is beginning that process up here and I appreciate it.

Senator THUNE. Let me ask you, what concerns do you have about advertising to children and how has the emergence of the tobacco companies in the e-cigarette field changed the market or the perception of the advertising?

Mr. BALLIN. For me, being from the public health community, I have the same concerns that many in public health have; about advertising crossing a line. Now, I don't know where that is, necessarily, but I will say that some of the things I've seen bother me as a public health person. But I don't think banning advertising per se is the route to go because, at the same time, I think we need to be providing truthful accurate information to the 40 million smokers out there about what these products are and how they can be used. That is, I think, where we need to go.

So I agree that we need monitor this stuff, which is what I just said earlier; there are things that give me heartburn about what I see in the marketplace, and I think we need to deal with them up front and in a very honest manner.

Senator THUNE. Just very quickly, Mr. Healey and Mr. Weiss, what are your companies doing to restrict advertising to children?

Mr. HEALEY. As I mentioned briefly, we adopted, with blu, a policy that we got from the Tobacco Control Act, and that was that in our print and television and marketing efforts that the audience be at least 85 percent adult; as I said, which is what we decided to impose and got that from the Tobacco Control Act.

Mr. WEISS. In NJOY's case, we also self-regulated. So, in the years that's led up to this regulation, we only advertise in programming that would have a predominantly adult audience whether that be on television or in print.

Senator THUNE. Mr. Chairman, my time has expired. Thanks.

The CHAIRMAN. Senator Heller, you're going to be a very good person, as you are anyway, and yield to Senator Boxer because she's the Committee Chair and she's here. And, oh, Senator Heller is not.

Senator Boxer.  
[Laughter.]

**STATEMENT OF HON. BARBARA BOXER,  
U.S. SENATOR FROM CALIFORNIA**

Senator BOXER. Thank you.

Mr. Ballin, you're a very optimistic man. You're talking about sitting around a table and resolving these things; we tried it with the tobacco companies. Do you know what it took? They all sat across

there in a different venue, in Congress, raised their hands, swore to tell the truth and then lied. And at that point, everyone turned and things began to happen and we began to make progress at that point.

And I just want to say, we don't ask people to raise their hands because you just need to know and we all know you have to tell the truth because of 18 U.S.C. 1001.

So I've heard a couple of things here that are not true. And I just want to talk about those things.

For example, I think Mr. Healey, you said in your—well, it's true. It's your opinion. This is the greatest invention ever to get people off of the other cigarettes. You said that.

Mr. HEALEY. Yes, Senator.

Senator BOXER. You did. Well, I may ask unanimous consent to place into the record, an American Heart Association peer-reviewed scientific journal; have you seen this, sir?

Mr. HEALEY. I don't believe I have, Senator.

Senator BOXER. OK, we'll get it to you. We'll put it into the record unless there are objections. OK.

[The information referred to follows and can also be found at <http://circ.ahajournals.org>.]

## Contemporary Reviews in Cardiovascular Medicine

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### E-Cigarettes A Scientific Review

Rachel Grana, PhD, MPH; Neal Benowitz, MD; Stanton A. Glantz, PhD

**E**lectronic cigarettes (e-cigarettes) are products that deliver a nicotine-containing aerosol (commonly called vapor) to users by heating a solution typically made up of propylene glycol or glycerol (glycerin), nicotine, and flavoring agents (Figure 1) invented in their current form by Chinese pharmacist Hon Lik in the early 2000s.<sup>1</sup> The US patent application describes the e-cigarette device as “an electronic atomization cigarette that functions as substitutes [sic] for quitting smoking and cigarette substitutes” (patent No. 8,490,628 B2). By 2013, the major multinational tobacco companies had entered the e-cigarette market. E-cigarettes are marketed via television, the Internet, and print advertisements (that often feature celebrities)<sup>2</sup> as healthier alternatives to tobacco smoking, as useful for quitting smoking and reducing cigarette consumption, and as a way to circumvent smoke-free laws by enabling users to “smoke anywhere.”<sup>3</sup>

There has been rapid market penetration of e-cigarettes despite many unanswered questions about their safety, efficacy for harm reduction and cessation, and total impact on public health. E-cigarette products are changing quickly, and many of the findings from studies of older products may not be relevant to the assessment of newer products that could be safer and more effective as nicotine delivery devices. In addition, marketing and other environmental influences may vary from country to country, so patterns of use and the ultimate impact on public health may differ. The individual risks and benefits and the total impact of these products occur in the context of the widespread and continuing availability of conventional cigarettes and other tobacco products, with high levels of dual use of e-cigarettes and conventional cigarettes at the same time among adults<sup>4-8</sup> and youth.<sup>9-11</sup> It is important to assess e-cigarette toxicant exposure and individual risk, as well as the health effects, of e-cigarettes as they are actually used to ensure safety and to develop an evidence-based regulatory scheme that protects the entire population—children and adults, smokers and nonsmokers—in the context of how the tobacco industry is marketing and promoting these products. Health claims and claims of efficacy for quitting smoking are unsupported by the scientific evidence to date. To minimize the potential negative

impacts on prevention and cessation and the undermining of existing tobacco control measures, e-cigarette use should be prohibited where tobacco cigarette use is prohibited, and the products should be subject to the same marketing restrictions as tobacco cigarettes.

#### Methods

Initial searches conducted via PubMed using the key words electronic cigarette, e-cigarette, and electronic nicotine delivery systems yielded 151 studies (Figure 2). Seventy-one articles presented original data and were included. Eighty articles were excluded because they were not relevant, were not in English, or were reviews or commentaries that did not provide original data, although some are cited for background and context. Searches using the same search terms were conducted using World Health Organization regional databases; only BIBLIOTECA Virtual em Saude Latin America and Caribbean included relevant papers, all of which had already been located with PubMed. Working with the World Health Organization, we also contacted investigators to locate other studies, some of which had not yet been published (submitted or in press). We also reviewed technical reports prepared by health organizations,<sup>12-15</sup> news articles, and relevant Web sites. The results of these searches were used to prepare a report commissioned by the World Health Organization Tobacco Free Initiative, which provides details of individual studies, including some studies that are not discussed in this article because of length constraints.<sup>1</sup> After the manuscript was submitted for peer review, 5 more articles became available, resulting in a total of 82 articles forming the basis for this review.

#### The Product

E-cigarette devices are manufactured mainly in China. As of late 2013, there was wide variability in e-cigarette product engineering, including varying nicotine concentrations in the solution used to generate the nicotine aerosol (also called e-liquid), varying volumes of solution in the product, different carrier compounds (most commonly propylene glycol with or without glycerol [glycerin]), a wide range of additives and flavors, and battery voltage. Quality control is variable,<sup>16</sup> and users can modify many of the products, including using them to deliver other drugs such as marijuana.<sup>17,18</sup> These engineering differences result in variability in how e-cigarettes heat and convert the nicotine solution to an aerosol and consequently the levels of nicotine and other

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| Product   | Description   | Some Brands  |
|---|---|--|
| <br><b>Disposable e-cigarette</b>                            | Cigarette-shaped device consisting of a battery and a cartridge containing an atomizer to heat a solution (with or without nicotine). Not rechargeable or refillable and is intended to be discarded after product stops producing aerosol. Sometimes called an e-hookah. | NJOY<br>OneJoy, Aer<br>Disposable,<br>Flavorvapes    |
| <br><b>Rechargeable e-cigarette</b>                          | Cigarette-shaped device consisting of a battery that connects to an atomizer used to heat a solution typically containing nicotine. Often contains an element that regulates puff duration and /or how many puffs may be taken consecutively.                             | Blu,<br>GreenSmoke,<br>EonSmoke                      |
| <br><b>Pen-style, medium-sized rechargeable e-cigarette</b>  | Larger than a cigarette, often with a higher capacity battery, may contain a prefilled cartridge or a refillable cartridge (often called a clearomizer). These devices often come with a manual switch allowing to regulate length and frequency of puffs.                | Vapor King<br>Storm,<br>Totally<br>Wicked<br>Tornado |
| <br><b>Tank-style, large-sized rechargeable e-cigarette</b> | Much larger than a cigarette with a higher capacity battery and typically contains a large, refillable cartridge. Often contains manual switches and a battery casing for customizing battery capacity. Can be easily modified.   | Volcano<br>Lavatube                                  |

Figure 1. Examples of different electronic cigarette (e-cigarette) products. Reproduced from Grana et al.<sup>1</sup>

chemicals delivered to users and the air pollution generated by the exhaled aerosol.<sup>19</sup>

E-liquids are flavored, including tobacco, menthol, coffee, fruit, candy, and alcohol flavors, as well as unusual flavors such as cola and Belgian waffle.<sup>3</sup> Flavored (conventional) tobacco products are used disproportionately by youth and initiators,<sup>20</sup> and cigarettes with characterizing flavors (except menthol) have been banned in the United States.

#### Marketing and Media Research

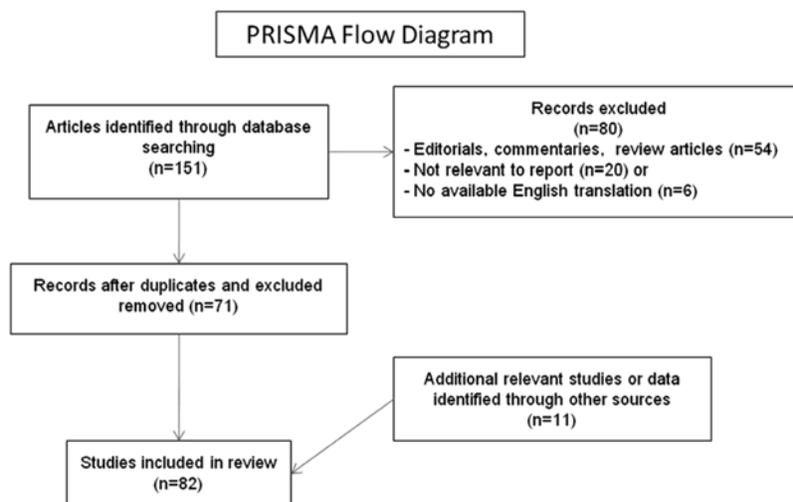
Consumer perceptions of the risks and benefits and decisions to use e-cigarettes are heavily influenced by how they are marketed. Celebrities have been used to market e-cigarettes since at least 2009.<sup>21</sup> Grana and Ling<sup>3</sup> reviewed 59 single-brand e-cigarette retail Web sites in 2012 and found that the most popular claims were that the products are healthier (95%), cheaper (93%), and cleaner (95%) than cigarettes; can be smoked anywhere (88%); can be used to circumvent smoke-free policies (71%); do not produce secondhand smoke (76%); and are modern (73%). Health claims made through text and pictorial and video representations of doctors were present on 22% of sites. Cessation-related claims (direct and indirect statements) were found on 64% of sites. Marketing on the sites commonly stated that e-cigarettes produce only “harmless

water vapor.” Similar messaging strategies were being used in the United Kingdom.<sup>22</sup>

These marketing messages have been repeated in the media. A thematic analysis of newspaper and online media coverage about e-cigarettes in the United Kingdom and Scotland from July 2007 to June 2012 found 5 themes: healthier choice, circumventing smoke-free restrictions, celebrity use, price, and risk and uncertainty.<sup>23</sup> Coverage often included anecdotes about having tried nicotine replacement therapies (NRTs), failing to quit, and then trying the e-cigarette (such as the celebrity endorsement by actress Katherine Heigl on the US David Letterman television program<sup>21</sup>), implying that e-cigarettes are a more effective form of NRT.

E-cigarette companies also have a strong presence in social media, which reinforces their marketing messages, including repeating the use of celebrity endorsements (eg, Heigl) and spreading images of the UK musical group Girls Aloud “puffing on e-cigarettes to cope with the stress of their 10th anniversary tour.”<sup>22</sup>

Cigarette and other tobacco companies have been unable to market their products on television and radio since the 1970s. E-cigarette advertising on television and radio is mass marketing of an addictive nicotine product for use in a recreational manner to new generations who have never experienced such marketing. In an online convenience sample of 519 adult



**Figure 2.** Studies screened and selected for inclusion. PRISMA indicates Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

smokers and recent quitters who viewed a television commercial for Blu e-cigarettes, 76% of current smokers reported that the ad made them think about smoking cigarettes, 74% reported it made them think about quitting, and 66% said it made them likely to try an e-cigarette in the future.<sup>24</sup> The 34% of participants who had used e-cigarettes were significantly more likely to think about smoking cigarettes after viewing the ad than nonusers (83% and 72%, respectively), suggesting that viewing an e-cigarette commercial may induce thoughts about smoking and cue the urge to smoke.<sup>24</sup>

### Prevalence

Awareness of e-cigarettes and e-cigarette trial have at least doubled among both adults and adolescents in several countries from 2008 to 2012. In the United States, awareness is more prevalent among men, but trying e-cigarettes is more prevalent among women. Almost the same percent of European Union and US adult respondents to national surveys reported having tried e-cigarettes (7% in 2012 versus 6.2% in 2011, respectively).<sup>5,25</sup> All population-based studies of adult use show the highest rate of e-cigarette use among current smokers, followed by former smokers, with little use among nonsmokers, although e-cigarette trial and use rose in all of these categories.<sup>4-6</sup> Etter and Bullen<sup>26</sup> followed up a sample of e-cigarette users recruited from Web sites dedicated to e-cigarettes and smoking cessation, most (72%) of whom were former smokers at baseline. At the 1-year follow up, 6% of former smokers who were daily e-cigarette users at baseline relapsed to smoking cigarettes, and almost all (92%) of

the former smokers using e-cigarettes daily at baseline were still using e-cigarettes daily at follow-up. Among 36 dual users at baseline, 16 (44%) had stopped smoking after 1 year. The epidemiological, population-based studies indicate that, across countries, e-cigarettes are most commonly being used concurrently with conventional tobacco cigarettes (dual use). Consistent with marketing messages, the most common reasons given for trying e-cigarettes are for use in places where smoking is restricted, to cut down on smoking, and for help with quitting smoking.<sup>6,27-30</sup>

Choi and Forster<sup>31</sup> followed up a cohort of Midwestern young adults (mean age, 24.1 years) who had never used e-cigarettes from 2010 to 2011 and found that 21.6% of baseline current smokers, 11.9% of baseline former smokers, and 2.9% of baseline nonsmokers reported having ever used e-cigarettes at follow-up. Those who believed at baseline that e-cigarettes could help with quitting smoking and perceived e-cigarettes to be less harmful than cigarettes were more likely to report experimenting with e-cigarettes at follow-up (adjusted odds ratio [OR], 1.98; 95% confidence interval [CI], 1.29–3.04; and adjusted OR, 2.34; 95% CI, 1.49–3.69, respectively).

Data on e-cigarette use among adolescents are more limited but, like for adults, show rapid increases in awareness and use in 5 countries (United States, Poland, Latvia, Finland, and Korea), with higher rates of trial and current use in European countries than the United States or Korea.<sup>9,10,32,33</sup> In Korea, youth ever use of e-cigarettes rose from 0.5% in 2008 to 9.4% in 2011,<sup>10</sup> and in the United States, it rose from 3.3% in 2011 to 6.8% in 2012.<sup>9</sup> As with adult population-based studies, data

suggest that e-cigarette use is most appealing and prevalent among youth who are also experimenting with or are current users of tobacco cigarettes. Dual use with conventional cigarettes is the predominant pattern of e-cigarette use: 61% in US middle school students and 80% among US high school students in 2011.<sup>9</sup> These results indicate rapid market penetration of e-cigarettes among youth, with trial among US high school students (10.0%) in 2012 even higher than the 2011 rate for adults (6.2%).<sup>9</sup> Despite a law prohibiting e-cigarette sales to minors, e-cigarette use among Utah youth (grades 8, 10, and 12) tripled between 2011 and 2013, with youth 3 times more likely to report current e-cigarette use than adults.<sup>34</sup>

Although dual use with cigarettes is high, some youth experimenting with e-cigarettes have never tried a tobacco cigarette, which indicates that some youth are initiating use of nicotine, an addictive drug, with e-cigarettes. In 2012, 20.3% of middle school and 7.2% of high school ever e-cigarette users reported never smoking conventional cigarettes.<sup>9</sup> Similarly, in 2011 in Korea, 15% of students in grades 7 through 12 who had ever used e-cigarettes had never smoked a cigarette.<sup>10</sup> The Utah Department of Health found that 32% of ever e-cigarette users reported that they had never smoked conventional cigarettes.<sup>34</sup>

### E-Cigarette E-Fluid and Vapor

#### Chemical Constituents

The nicotine content of the cartridge e-liquid from some brands revealed poor concordance of labeled and actual nicotine content.<sup>35–39</sup> Simulated e-cigarette use revealed that individual puffs contained from 0 to 35 µg nicotine per puff.<sup>37</sup> Assuming a high nicotine delivery of 30 µg per puff, it would take ≈30 puffs to deliver the 1 mg nicotine typically delivered by smoking a conventional cigarette. A puff of the e-cigarette with the highest nicotine content contained 20% of the nicotine contained in a puff of a conventional cigarette.<sup>37</sup> Actual nicotine delivery from an e-cigarette would likely be affected by users' smoking behavior. An analysis of UK brand e-cigarettes and the resulting aerosol demonstrated that, across brands, nicotine content of the e-liquid in the cartridges was not significantly correlated with the amount found in the

resulting aerosol, indicating differences in the engineering characteristics of the device that strongly influence nicotine delivery even with a consistent puffing protocol.<sup>40</sup>

Goniewicz et al<sup>41</sup> analyzed the aerosol from 12 brands of e-cigarettes, a conventional cigarette, and a nicotine inhaler for toxic and carcinogenic compounds. The levels of toxicants in the aerosol were 1 to 2 orders of magnitude lower than in cigarette smoke but higher than with a nicotine inhaler (Table 1).

Kim and Shin<sup>42</sup> analyzed the tobacco-specific nitrosamines NNN, NNK, and NAT and total tobacco-specific nitrosamines in 105 refill fluids from 11 companies in the Korean market and found nearly a 3-order-of-magnitude variation in tobacco-specific nitrosamine concentrations, with total tobacco-specific nitrosamine concentration ranging from 330 to 8600 µg/mL.

#### Cytotoxicity

Bahl et al<sup>43</sup> screened 41 e-cigarette refill fluids from 4 companies for cytotoxicity using 3 cell types: human pulmonary fibroblasts, human embryonic stem cells, and mouse neural stem cells. Cytotoxicity varied among products from highly toxic to low or no cytotoxicity. The authors determined that nicotine did not cause cytotoxicity, that some products were noncytotoxic to pulmonary fibroblasts but cytotoxic to both types of stem cells, and that cytotoxicity was related to the concentration and number of flavorings used. The finding that the stem cells are more sensitive than the differentiated adult pulmonary fibroblasts cells suggests that adult lungs are probably not the most sensitive system to assess the effects of exposure to e-cigarette aerosol. These findings also raise concerns about pregnant women who use e-cigarettes or are exposed to secondhand e-cigarette aerosol.

In a study funded by the FlavorArt e-cigarette liquid manufacturers, Romagna et al<sup>44</sup> compared the cytotoxicity of aerosol produced from 21 nicotine-containing, flavored (12 tobacco flavored and 9 fruit or candied flavored) brands of e-cigarette liquid with smoke from a conventional cigarette using embryonic mouse fibroblast cells. Only aerosol from coffee-flavored e-liquid produced a cytotoxic effect (average, 51% viability at 100% concentration of solution).

**Table 1. Levels of Toxicants in E-Cigarette Aerosol Compared With Nicotine Inhaler and Cigarette Smoke**

| Toxicant                 | Range in Content in Aerosol From 12 E-Cigarette Samples per 15 Puffs* | Range in Content in Conventional Cigarette Micrograms in Mainstream Smoke From 1 Cigarette | Content in Nicotine Inhaler Mist per 15 Puffs* |
|--------------------------|---|--|--|
| Formaldehyde, µg         | 0.2–5.61  | 1.6–52   | 0.2  |
| Acetaldehyde, µg         | 0.11–1.36   | 52–140   | 0.11   |
| Acrolein, µg             | 0.07–4.19   | 2.4–62   | ND   |
| o-Methylbenzaldehyde, µg | 0.13–0.71   | ...  | 0.07   |
| Toluene, µg              | ND–0.63   | 8.3–70   | ND   |
| p,m-xylene, µg           | ND–0.2  | ...  | ND   |
| NNN, ng                  | ND–0.00043  | 0.0005–0.19  | ND   |
| NNK, ng                  | ND–0.00283  | 0.012–0.11   | ND   |
| Cadmium, ng              | ND–0.022  | ...  | 0.003  |
| Nickel, ng               | 0.011–0.029   | ...  | 0.019  |
| Lead, ng                 | 0.003–0.057   | ...  | 0.004  |

Prepared using data from Goniewicz et al.<sup>41</sup> E-cigarette indicates electronic cigarette; and ND, not determined.

Farsalinos et al<sup>45</sup> tested cytotoxicity in cultured rat cardiac myoblasts of exposure to aerosol generated from 20 refill solutions from 5 manufacturers containing 6 to 24 mg/mL nicotine in various flavors, a "base"-only solution (50% propylene glycol and 50% glycerol), and conventional cigarette smoke. The aerosol from 3 fluids was cytotoxic at 100% and 50% dilution; 2 were tobacco flavored and 1 was cinnamon cookie flavored. Cigarette smoke was cytotoxic at 100% and all dilutions except 6.25%.

### Secondhand Exposure

E-cigarettes do not burn or smolder the way conventional cigarettes do, so they do not emit side-stream smoke; however, bystanders are exposed to aerosol exhaled by the user. Schripp et al<sup>46</sup> conducted chamber studies in which subjects used 3 e-liquids (0 mg nicotine, apple flavor; 18 mg nicotine, apple flavor; 18 mg nicotine, tobacco flavor) and 1 tobacco cigarette and measured levels of several toxins and nicotine in the resulting aerosol. Three e-cigarette devices were used for these experiments: 2 that used a tank system that is directly filled with e-liquid and one that used a cartridge with a cotton fiber on which to drip the liquid. They found low levels of formaldehyde, acetaldehyde, isoprene, acetic acid, 2-butanodione, acetone, propanol, propylene glycol, and diacetyl (from flavoring), traces of apple oil (3-methylbutyl-3-methylbutanoate), and nicotine (with differing levels depending on the specific protocols) emitted into the air. Toxins in the e-cigarette aerosol were at much lower levels compared with the conventional cigarette emissions.<sup>46</sup>

In another chamber study, Flouris et al<sup>47</sup> compared emissions of conventional cigarettes and e-cigarettes in conditions designed to approximate a smoky bar (target air CO of 23 ppm) using machine-smoked e-cigarettes and cigarettes. E-cigarette aerosol (using a single brand of e-cigarette made in Greece and a single e-liquid with at least 60% propylene glycol, 11 mg/mL nicotine) was generated with a pump that operated for the same duration as the cigarette smoking, and aerosol was released into the room. (A person inhaling a nicotine aerosol usually absorbs 80% of the nicotine,<sup>48</sup> whereas the pump discharges all nicotine into the environment, so the nicotine exposure may be higher in this study than would be the case with actual secondhand aerosol exposure.) Serum cotinine in nonsmokers sitting in the chamber was similar for cigarette smoke and e-cigarette aerosol exposure (average, 0.8 ng/mL for tobacco cigarette and 0.5 ng/mL for e-cigarette).

Schober et al<sup>49</sup> measured indoor pollution from 3 people using e-cigarettes over a 2-hour period in a realistic environment modeled on a café. They found elevated nicotine, 1,2-propanediol, glycerin, aluminum, and 7 polycyclic aromatic hydrocarbons classified as probable carcinogens by the International Agency for Research on Cancer in the room air.

Czogala et al<sup>49</sup> conducted a chamber study of secondhand exposure to e-cigarette aerosol compared with cigarette smoke, finding that, on average, bystanders would be exposed to nicotine but at levels 1/10th that of cigarette smoke (e-cigarette aerosol, 3.32±2.49 µg/m<sup>3</sup>; cigarette smoke, 31.60±6.91 µg/m<sup>3</sup>; *P*=0.008). Both e-cigarette aerosol and cigarette smoke contained fine particles (PM<sub>2.5</sub>), with e-cigarette aerosol particle concentrations ranging from 6.6 to 85.0 µg/m<sup>3</sup>. E-cigarette

aerosol was not a source of exposure to carbon monoxide, a key combustion element of conventional cigarette smoke.

### Particulate Matter

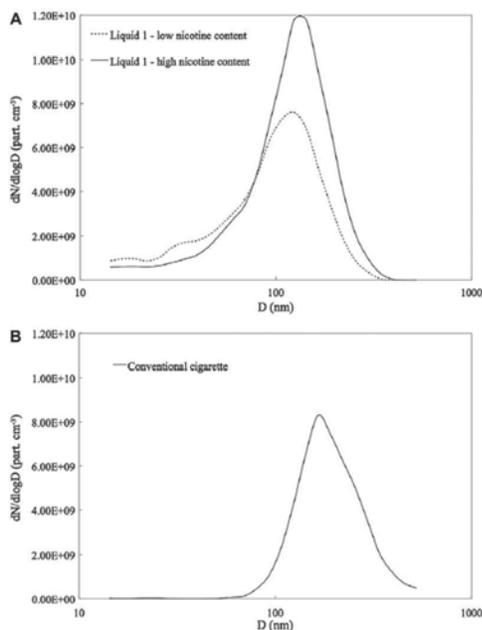
E-cigarettes deliver nicotine by creating an aerosol of ultrafine particles. Fine particles can be variable and chemically complex, and the specific components responsible for toxicity and the relative importance of particle size and particle composition are generally not known.<sup>50</sup> Given these uncertainties, it is not clear whether the ultrafine particles delivered by e-cigarettes have health effects and toxicity similar to the ambient fine particles generated by conventional cigarette smoke or secondhand smoke. There is strong evidence, however, that frequent low or short-term levels of exposure to fine and ultrafine particles from tobacco smoke or air pollution can contribute to pulmonary and systemic inflammatory processes and increase the risk of cardiovascular and respiratory disease and death.<sup>51-54</sup>

Fuoco et al<sup>55</sup> examined particle number concentration and distribution and performed a volatility analysis of the e-cigarette aerosol generated from 3 devices (2 rechargeable and 1 disposable) using 4 refill e-liquids with varying levels of nicotine and flavorants. They found that higher e-liquid nicotine content was associated with higher particle numbers in the resulting aerosol, with little effect on the particle size distribution. Longer puffing time resulted in more particles. Flavor was not associated with differences in particle number or size distribution. Consistent with other studies,<sup>46,56-58</sup> the particle size distribution (range of modes, ≈120–165 nm) was similar to that of conventional cigarettes, with some e-cigarettes delivering more particles than conventional cigarettes (Figure 3).

Zhang et al<sup>57</sup> examined the size of e-cigarette aerosol particles and likely deposition in the human body (using a single brand, BloogMaxXFusion) with both propylene glycol and vegetable glycerin-based liquids. Using particle size and lung ventilation rates (1 for a "reference worker" and 1 for a "heavy worker": 1.2 and 1.688 m<sup>3</sup>/h, respectively), their human deposition model estimated that 73% to 80% of particles would be distributed into the exhaled aerosol, whereas 9% to 18% of particles would be deposited in alveoli resulting in arterial delivery, and 9% to 17% would be deposited in the head and airways, resulting in venous delivery. As expected, the heavy worker model showed more alveolar delivery across puffs compared with the reference worker, who would have more head and airway delivery. In total, ≈20% to 27% of particles are estimated to be deposited in the circulatory system and into organs from e-cigarette aerosol, which is comparable to the 25% to 35% for conventional cigarette smoke.

In their study of passive exposure to exhaled e-cigarette aerosol in a simulated café, Schober et al<sup>49</sup> found that concentrations of fine particles in the air increased from a median of 400 particles per 1 cm<sup>3</sup> with people simply sitting in the room for 2 hours to medians of 49 000 to 88 000 particles per 1 cm<sup>3</sup> (depending on the e-cigarette fluid used) after 2 hours of e-cigarette use in the same room.

Both the e-liquid and the Poly-fil fibers that are used to absorb the e-liquid for heating and conversion to an aerosol come into contact with heating elements that contain heavy



**Figure 3.** Particle number distribution from (A) mainstream aerosol in e-liquid 1 and from (B) conventional cigarette. Reproduced from Fuoco et al<sup>55</sup> with permission from the publisher. Copyright © 2013 Elsevier Ltd.

metals (tin, nickel, copper, lead, chromium). Williams et al<sup>58</sup> found heavy metals in samples of e-cigarette liquids and aerosol. Tin, which appeared to originate from solder joints, was found as both particles and tin whiskers in the fluid and Poly-fil, and e-cigarette fluid containing tin was cytotoxic to human pulmonary fibroblasts. E-cigarette aerosol also contained other metals, including nickel, 2 to 100 times higher than found in Marlboro cigarette smoke. The nickel and chromium nanoparticles (<100 nm) possibly originated from the heating element. It is likely that engineering features, including the nature of the battery, the heating temperature of the liquid, and the type of heating element and reservoir, will influence the nature, number, and size of particles produced. These metal nanoparticles can deposit into alveolar sacs in the lungs, potentially causing local respiratory toxicity and entering the bloodstream.

In summary, the particle size distribution and number of particles delivered by e-cigarettes are similar to those of conventional cigarettes, with most particles in the ultrafine range (modes,  $\approx 100$ –200 nm). Particle delivery appears to depend on the nicotine level in the e-cigarette fluid but not the presence of flavors. Smokers exhale some of these particles, which exposes bystanders to “passive vaping.” Like cigarettes, e-cigarette particles are small enough to reach deep into the

lungs and cross into the systemic circulation. At a minimum, these studies show that e-cigarette aerosol is not merely “water vapor” as is often claimed in the marketing for these products. Tests on e-cigarettes show much lower levels of most toxicants, but not particles, than conventional cigarettes. The thresholds for human toxicity of potential toxicants in e-cigarette vapor are not known, and the possibility of health risks to primary users of the products and those exposed passively to their emissions must be considered.

#### Nicotine Absorption

Early studies of nicotine absorption in 2010 found that e-cigarettes delivered much lower levels of plasma nicotine than conventional cigarettes,<sup>59,60</sup> whereas a more recent study demonstrated that more experienced users using their own product who engaged in more puff intervals have nicotine absorption similar to that with conventional cigarettes,<sup>61–63</sup> perhaps as a result of a combination of characteristics of the devices and user vaping topography.<sup>63</sup> Another study of smokers smoking e-cigarettes using a specified protocol found a similar rise in serum cotinine immediately after use (mean increase,  $\approx 20$  ng/mL).<sup>47</sup> Several studies reported that regardless of nicotine delivery, e-cigarettes can modestly alleviate some symptoms of withdrawal, and participants positively

appraised the use of e-cigarettes.<sup>62-65</sup> In a study comparing the nicotine inhalator and e-cigarettes,<sup>60</sup> the nicotine inhalator delivered an amount of nicotine similar to that in the 16-mg e-cigarette; however, the authors noted that the e-cigarette malfunctioned and did not deliver any nicotine in a third of participants. These results highlight the need for product regulation in terms of drug delivery and effects, as well as device functioning and labeling.

### Health Effects

Propylene glycol and glycerin are the main base ingredients of the e-liquid. Exposure to propylene glycol can cause eye and respiratory irritation, and prolonged or repeated inhalation in industrial settings may affect the central nervous system, behavior, and the spleen.<sup>66</sup> In its product safety materials, Dow Chemical Company states that "inhalation exposure to [propylene glycol] mists should be avoided,"<sup>66</sup> and the American Chemistry Council warns against its use in theater fogs because of the potential for eye and respiratory irritation.<sup>68</sup> When heated and vaporized, propylene glycol can form propylene oxide, an International Agency for Research on Cancer class 2B carcinogen,<sup>69</sup> and glycerol forms acrolein, which can cause upper respiratory tract irritation.<sup>70,71</sup>

Major injuries and illness have resulted from e-cigarette use,<sup>72</sup> including explosions and fires.<sup>73,74</sup> Less serious adverse events include throat and mouth irritation, cough, nausea, and vomiting.<sup>72</sup>

A study<sup>75</sup> of healthy smokers' pulmonary function after acute ad lib puffing of an e-cigarette (Nobacco, medium, 11 mg) for 5 minutes (after refraining from smoking tobacco cigarettes for 4 hours) found no effect on spirometry but did find significantly increased dynamic airway resistance (18%) and decreased expired nitric oxide (16%). Sham e-cigarette use had no significant effect. This study is limited by the small sample size, the short period of tobacco use abstinence before protocol execution, the short length of exposure to e-cigarette aerosol, and the lack of comparison with smoking conventional cigarettes. In addition, smokers in general have high airway resistance with dynamic testing and lower expired nitric oxide, likely as a result of oxidant stress. Despite these limitations, this study suggests that e-cigarette use constricts peripheral airways, possibly as a result of the irritant effects of propylene glycol, which could be of particular concern in people with chronic lung disease such as asthma, emphysema, or chronic bronchitis.

Flouris et al<sup>47</sup> assessed the short-term effects of e-cigarette use on pulmonary function in 15 cigarette smokers who puffed an e-cigarette (>60% propylene glycol, 11 mg/mL nicotine) and a conventional cigarette according to a specified protocol, and passive exposure to e-cigarette aerosol and conventional cigarette smoke with 15 never smokers. Active cigarette smoking resulted in a significant decrease in expired lung volume (forced expiratory volume in the first second of expiration/forced inspiratory vital capacity) that was not seen with active e-cigarette use or with passive tobacco cigarette or e-cigarette exposure. Additional analysis of the data collected in this study<sup>76</sup> found that white cell count increased after cigarette smoking, reflecting inflammatory process-associated risk for acute cardiovascular events. Active e-cigarette use and

passive exposure to e-cigarette vapor did not result in a significant increase in these biomarkers over 1 hour of exposure.

Schober et al<sup>39</sup> found elevated levels of exhaled nitric oxide in people using a nicotine e-cigarette (but not a nicotine-free e-cigarette), which the authors attributed to pulmonary inflammation.

National Vaper's Club, a pro-e-cigarette advocacy group, published a "risk assessment" of e-cigarette and cigarette use that concluded that "neither vapor from e-liquids or cigarette smoke analytes posed a condition of 'significant risk' of harm to human health via the inhalation route of exposure."<sup>77</sup> The authors failed to detect benzo(a)pyrene in conventional cigarette smoke despite the fact that it is an established carcinogen in cigarette smoke, and their assessment of conventional cigarettes concluded that they did not pose significant risk, both of which point to fatal errors in the data, data analysis, or both. Another report<sup>15</sup> funded by the Consumer Advocates for Smoke-free Alternatives Association and published on the Internet used occupational threshold limit values to evaluate the potential risk posed by several toxins in e-cigarettes, concluding that "there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces." Threshold limit values are an approach to assessing health effects for occupational chemical exposures that are generally much higher (often orders of magnitude higher) than levels considered acceptable for ambient or population-level exposures. Occupational exposures also do not consider exposure to sensitive subgroups such as people with medical conditions, children, and infants who might be exposed to secondhand e-cigarette emissions, most notably nicotine.

In summary, only a few studies have directly investigated the health effects of exposure to e-cigarette aerosol, but some demonstrate the ability of e-cigarette aerosol exposure to result in biological effects. Long-term biological effects are unknown at this time because e-cigarettes have not been in widespread use long enough for assessment.

### Effects on Cessation of Conventional Cigarettes

E-cigarettes are promoted as smoking cessation aids, and many individuals who use e-cigarettes believe that they will help them quit smoking conventional cigarettes.<sup>7,29,30</sup> The assumption that e-cigarettes will be as effective as or more effective than pharmaceutical NRTs has also motivated support for e-cigarettes among some public health researchers and policy makers<sup>78</sup> and (as discussed later) formed the basis for some public policies on the regulation of e-cigarettes.

### Population-Based Studies

There are 4 longitudinal studies<sup>4,79-81</sup> and 1 cross-sectional study<sup>82</sup> of the association between e-cigarette use and quitting conventional cigarettes (Table 2).

Adkison et al<sup>4</sup> studied current and former smokers in the *International Tobacco Control* study in the United States, Canada, the United Kingdom, and Australia at baseline and 1 year later and found that e-cigarette users had a statistically significant greater reduction in cigarettes per day (e-cigarette users, 20.1 to 16.3 cigarettes per day; nonusers, 16.9 to 15.0

**Table 2. Population Studies of the Association Between E-Cigarette Use and Cessation of Conventional Cigarette Smoking**

| Study                                 | Location and Study Design  | Odds of Quitting (95% CI) |
|---------------------------------------|--|---------------------------|
| Longitudinal studies                  |  |                           |
| Adkison et al <sup>4</sup> (2013)     | US, UK, Canada, Australia (ITC), surveyed, 1 y apart                       | 0.81 (0.43–1.53)*         |
| Vickerman et al <sup>10</sup> (2013)  | US quit-line callers from 6 states surveyed at enrollment and 7 mo later   | 0.50 (0.40–0.63)†         |
| Grana et al <sup>19</sup> (2014)      | US sample drawn from a nationally representative Internet panel, 1 y apart | 0.76 (0.36–1.60)          |
| Choi and Forster <sup>31</sup> (2014) | Midwestern young adults, 1 y apart   | 0.93 (0.19–4.63)          |
| Cross-sectional study                 |  |                           |
| Popova and Ling <sup>82</sup> (2013)  | US sample drawn from a nationally represented Internet panel               | 0.69 (0.52–0.94) *        |
| All studies                           |  |                           |
| Pooled‡                               |  | 0.61 (0.50–0.75)          |

CI indicates confidence interval; E-cigarette, electronic cigarette; and ITC, International Tobacco Control.

\*Odds ratios obtained by contacting authors.

†Computed by authors of this report on the basis of the numbers reported.

‡Estimated with a random-effects meta-analysis using Stata 12.1 meta. There was no evidence of heterogeneity ( $P=0.28$ ) or evidence of publication bias with the use of a funnel plot.

cigarettes per day). Although 85% of e-cigarette users reported they were using the product to quit smoking at the initial wave, e-cigarette users were no more likely to have quit 1 year later than nonsmokers (OR, 0.81; 95% CI, 0.43–1.53;  $P=0.52$ ).

Vickerman et al<sup>10</sup> found that ≈31% of quit-line callers surveyed 7 months after enrollment reported that they had ever tried e-cigarettes. The majority used them for <1 month (67.1%), and 9.2% were using them at the 7-month survey. The main reason for e-cigarette use was tobacco cessation (51.3%), but it is not known whether ever use occurred as part of a quit attempt in the preceding 7 months. Although quit-line callers represent a small population of smokers motivated to quit, these data present a real-world estimate of the potential effectiveness of using e-cigarettes for cessation in a population of smokers motivated to quit. Although this study had a low response rate (34.6%) and may be subject to recall bias because e-cigarette use and perceptions were assessed only at the 7-month follow-up, those who reported using e-cigarettes were statistically significantly less likely to quit than those who had not used e-cigarettes (21.7% among callers who used for ≥1 month, 16.6% among those who used for <1 month, and 31.4% among never users;  $P<0.001$ ). The unadjusted odds of quitting were statistically significantly lower for e-cigarette users compared with nonsmokers (OR, 0.50; 95% CI, 0.40–0.63).

Grana et al<sup>19</sup> explored predictors of quitting among a national sample of smokers who participated in a study in 2011 and follow-up in 2012. Current e-cigarette use (past 30 days) at baseline did not predict a greater likelihood of having quit at the follow-up (OR, 0.71; 95% CI, 0.35–1.46). In a second logistic regression model that included baseline cigarettes per day, time to first cigarette, and intention to quit, in addition to baseline current e-cigarette use, only intention to quit (OR, 5.59; 95% CI, 2.41–12.98) and cigarettes per day (OR, 0.97; 95% CI, 0.94–0.99) were significant predictors of having quit at follow-up; current e-cigarette use remained nonsignificant (OR, 0.76; 95% CI, 0.36–1.60).

Choi and Forster<sup>31</sup> followed up a cohort of young adults in Midwestern (recruited October 2010–March 2011 and followed up for 1 year). Among those who were smoking cigarettes at

baseline, 11% of those who used e-cigarettes at least 1 day in the past 30 days at baseline quit smoking at follow-up compared with 17% of smokers who never used e-cigarettes. In a logistic regression controlling for demographics and baseline cigarettes per day, baseline past 30-day e-cigarette use was not a significant predictor of having quit at follow-up (OR, 0.93; 95% CI, 0.19–4.63;  $P=0.93$ ). There was also no significant change in the number of conventional cigarettes smoked per day between those who did and did not use e-cigarettes (difference, 0.2 cigarettes per day; 95% CI, –3.72 to 4.18;  $P=0.91$ ).

In a national cross-sectional sample, Popova and Ling<sup>82</sup> found that adult smokers who ever used e-cigarettes were significantly less likely to be former smokers compared to those who never used e-cigarettes (OR, 0.69; 95% CI, 0.52–0.94), controlling for demographics (Lucy Popova, personal communication). In an examination of only those who tried to quit, those who ever used e-cigarettes were significantly less likely to be former smokers than never users (adjusted OR, 0.61; 95% CI, 0.45–0.83).

Combining these results in a random-effects meta-analysis (Table 2) yields a pooled OR of 0.61 (95% CI, 0.50–0.75), indicating that e-cigarette use in the real world is associated with significantly lower odds of quitting smoking cigarettes. A limitation of 3 of these studies<sup>4,10,82</sup> is that they did not control for level of nicotine dependence. It is possible that more dependent smokers, who would have more difficulty quitting in general, would be the ones who would be more likely to experiment with e-cigarettes, which could contribute to the finding that e-cigarette use is associated with a lower quit rate.

#### Clinical Trials

Four clinical trials (2 with very small samples) examined the efficacy of e-cigarettes for smoking cessation.<sup>83–86</sup> Three trials<sup>83–85</sup> did not have a control group who were not using e-cigarettes. The other study<sup>86</sup> compared e-cigarette efficacy to a standard-of-care regimen with a 21-mg nicotine patch. None of the trials were conducted with the level of behavioral support that accompanies most pharmaceutical trials for smoking cessation.

Polosa et al<sup>83</sup> conducted a proof-of-concept study in Italy in 2010 with smokers 18 to 60 years of age not intending to quit in the next 30 days. Subjects were offered Categoria e-cigarettes and instructed to use up to 4 cartridges (7.4-mg nicotine content) per day as desired to reduce smoking and to keep a log of cigarettes per day, cartridges per day, and adverse events. Six-month follow-up was completed with 68% of participants (27 of 40): 13 were using both e-cigarettes and tobacco cigarettes, 5 maintained exclusive tobacco cigarette smoking, and 9 stopped using tobacco cigarettes while continuing to use e-cigarettes. Cigarette consumption was reduced by at least 50% in the 13 dual users (25 cigarettes per day at baseline to 6 cigarettes per day at 6 months;  $P<0.001$ ). Polosa et al<sup>87</sup> continued follow-up of this sample at 18 and 24 months with 23 subjects (58% of the original 40 enrolled). Among the 23 participants who completed a 24-month visit, 18 continued to smoke, and 11 had reduced cigarette consumption by  $\geq 50\%$  with a statistically significant reduction from an average of 24 to 4 cigarettes per day ( $P=0.003$ ). Five participants had quit tobacco cigarettes at 24 months. Study limitations included the use of a poor-quality product and the lack of a comparison or control group, which could make it difficult to determine whether quit rates achieved were not due to chance.

Capponnetto et al<sup>85</sup> conducted a similar study with 14 smokers with schizophrenia not intending to quit in the next 30 days. Participants were provided the same Categoria e-cigarette, and carbon monoxide, product use, number of cigarettes smoked, and positive and negative symptoms of schizophrenia were assessed at baseline and 4, 8, 12, 24, and 52 weeks. Seven of 14 participants (50%) sustained a 50% reduction in the number of cigarettes per day smoked at week 52, and the median of 30 cigarettes per day decreased to 15 cigarettes per day ( $P=0.018$ ). Sustained abstinence from smoking occurred with 2 participants (14.3%) by week 52. Positive and negative aspects of schizophrenia were not increased after smoking cessation. The most common outcome was dual use of e-cigarettes with conventional cigarettes. Study findings are not generalizable to smokers with mental illness because of the very small sample size and lack of a control group.

Capponnetto et al<sup>84</sup> also conducted a randomized, quasi-controlled trial to examine the efficacy of e-cigarettes of different strengths for smoking cessation and reduction in 3 study arms: 12 weeks of treatment with the 7.2-mg nicotine e-cigarette, a 12-week nicotine-tapering regimen (6 weeks of treatment with a 7.2-mg e-cigarette and 6 weeks with a 5.4-mg e-cigarette), and a 12-week treatment with a nonnicotine e-cigarette. Similar reductions in the median cigarettes per day were seen at all study visits for all 3 treatment arms (7–10 cigarettes per day at 1 year). There was no statistically significant difference in 6-month or 1-year quit rate among the 3 conditions (1-year rates: 4% for placebo e-cigarette users, 9% for low-nicotine e-cigarette users, and 13% for high-nicotine e-cigarette users). The authors noted that those who initiated quitting in the first few weeks of the study stayed quitters, whereas those who did not remained dual users throughout the study. Twenty-six percent of quitters continued to use e-cigarettes at 1 year. Problems with the study include the lack of a control group not using e-cigarettes and noted lack of product quality (the devices malfunctioned often, and new

ones had to be sent frequently). An author on all of these studies, R. Polosa, served as a consultant for the Arbi Group SRL, the manufacturer of the Categoria e-cigarette used in the study, beginning in February 2011.

Bullen et al<sup>86</sup> conducted a randomized, controlled, clinical trial of e-cigarettes compared with medicinal NRT in Auckland, New Zealand. Adult smokers motivated to quit were randomized to the 3 study arms (16-mg e-cigarette, 21-mg NRT patch, no-nicotine e-cigarette). Voluntary telephone counseling was offered to all subjects. Subjects were observed at baseline, 1 week (quit day), 12 weeks, and 6 months. Fifty-seven percent of participants in the nicotine e-cigarettes group reduced their cigarettes per day by  $\geq 50\%$  at 6 months compared with 41% in the patch group ( $P=0.002$ ) and 45% in the nonnicotine e-cigarette group ( $P=0.08$ ). Those randomized to the nicotine patch group were less adherent to the treatment (46%) than the 16-mg e-cigarette group (78%) and the no-nicotine e-cigarette group (82%). Of note, the study methodology may have introduced bias against success in the nicotine patch group because e-cigarettes were mailed for free directly to participants randomized to either the nicotine or no-nicotine e-cigarette group, whereas participants in the patch group were mailed cards redeemable for nicotine patches at a pharmacy and vouchers to cover the modest fee. Therefore, although the protocol for providing the patches represented "usual care" for New Zealand quit-line callers, this procedure may have introduced bias against NRT, making it difficult to view the study as a head-to-head comparison of e-cigarettes and NRT for cessation. There were no statistically significant differences in biochemically confirmed (breath CO) self-reported continuous abstinence from quit day to the 6-month follow-up between the nicotine e-cigarette (7.3%), nicotine patch (5.8%), and nonnicotine e-cigarette (4.1%).

Neither Capponnetto et al<sup>84</sup> nor Bullen et al<sup>86</sup> found effects of e-cigarette use on quitting beyond what is seen in unassisted or low-assistance studies of smokers using NRT to quit.<sup>88</sup> In determining the effectiveness of smoking cessation therapy, active drug is considered efficacious when it outperforms placebo; therefore, the evidence to date from clinical trials does not demonstrate that e-cigarettes are efficacious for cessation. However, it is possible that e-cigarettes even without nicotine act as substitutes for the sensory and behavioral effects of conventional cigarettes. If this is the case, the nonnicotine placebo e-cigarette would be considered an active treatment condition and, as discussed previously, has been shown to reduce withdrawal symptoms.<sup>39,60,63,89</sup> Important limitations of the current research include the use of e-cigarettes that deliver relatively low levels of nicotine and the provision of minimal behavioral counseling. Another important limitation of studies assessing the effectiveness of e-cigarettes for smoking cessation is that, because they are not approved as cessation therapy, there are no therapeutic instructions for using them as replacements or to quit smoking (eg, dosage tapering, duration of use, how to combine them with behavioral strategies, guidance for discontinuation).

In contrast to the assumption that e-cigarettes would function as a better form of NRT, population-based studies that reflect real-world e-cigarette use found that e-cigarette use is not associated with successful quitting; all<sup>1,79,80,82</sup> had point

estimates of the odds of quitting of <1.0. The 1 clinical trial examining the effectiveness of e-cigarettes (both with and without nicotine) compared with the medicinal nicotine patch found that e-cigarettes are no better than the nicotine patch and that all treatments produced very modest quit rates without counseling.<sup>86</sup> Taken together, these studies suggest that e-cigarettes are not associated with successful quitting in general population-based samples of smokers.

#### Health Implications of Cigarette Reduction in the Context of Dual Use

Among adults, reductions in cigarettes per day were observed in several of the clinical studies<sup>83,84,86</sup> and in 1 population-based study<sup>4</sup> among those who did not quit. Reduction in cigarettes smoked per day could have benefit if it promotes subsequent cessation, as has been found with NRT,<sup>90</sup> but this pattern has not yet been seen with e-cigarettes. In the cigarette reduction analyses presented in some of the studies, many participants were still smoking about half a pack cigarettes per day at the end of the study.

Both duration (years of cigarette use) and intensity (cigarettes per day) determine the negative health effects of smoking.<sup>91</sup> People who stop smoking at younger ages have lower age-adjusted mortality compared with those who continued to smoke later into adulthood.<sup>92</sup> Findings for decreased smoking intensity have been less consistent, with some studies showing lower mortality with reduced daily cigarette consumption<sup>93</sup> and others not finding a significant overall survival benefit.<sup>94</sup> The 2014 report of the US Surgeon General concluded that “reducing the number of cigarettes smoked per day is much less effective than quitting entirely for avoiding the risks of premature death from all smoking-related causes of death.”<sup>95</sup> Use of electronic cigarettes by cigarette smokers to cut down on the number of cigarettes smoked per day is likely to have much smaller beneficial effects on overall survival compared with quitting smoking completely.

This situation is particularly likely to exist for cardiovascular disease because of the highly nonlinear dose-response relationship between exposure to fine particles and the risk of cardiovascular disease.<sup>53,96</sup> Light smoking, even 1 to 4 cigarettes per day, is associated with markedly elevated risk of cardiovascular disease.<sup>97</sup> In addition, e-cigarettes deliver loads of fine particles similar to those of conventional cigarettes.

The relative risk of death from lung cancer increases with years smoked and cigarettes per day,<sup>98</sup> as well as pancreatic cancer<sup>99</sup> and esophageal cancer.<sup>100</sup> The relative risk of both lung cancer and bladder cancer levels off after a certain number of cigarettes per day,<sup>101</sup> suggesting that above a certain intensity, the specific levels of exposure may not cause significant differences in risk for these cancers. Doll and Peto<sup>102</sup> found a dose-response relationship between duration of smoking and number of cigarettes smoked per day and risk of lung cancer, with models suggesting the impact of duration to be greater than that of intensity. Using participants from the Cancer Prevention Study II, Flanders et al<sup>103</sup> found a greater increase in lung cancer mortality with a greater duration of cigarette smoking compared with a greater intensity of smoking. Overall, these data suggest that lung cancer mortality increases more with additional years of smoking than

additional cigarettes per day. Thus, if dual use of e-cigarettes and cigarettes results in reductions in the number of cigarettes per day for current smokers, any reduction in malignancy risk will be less than proportional to the reduction in cigarette consumption because of the (likely larger) importance of duration of smoking.

#### What to Tell Patients About E-Cigarettes and Cessation

First and foremost, clinicians must support a smoker’s quit attempt and try to ensure any advice given does not undermine their motivation to quit. Clinicians should follow the 5 A’s of evidence-based treatment: ask, advise, assess, assist, and arrange.<sup>104</sup> They should assess their patient’s motivation and readiness to quit and recommend a treatment plan that should include setting a quit date and obtaining cessation counseling and, if appropriate, conventional smoking cessation medications. The safest and most proven smoking cessation pharmacotherapies are the nicotine replacement medications varenicline and bupropion, which have been approved by the US Food and Drug Administration (FDA). Referral to a free telephone quit line (eg, 1-800-QUIT-NOW) or another counseling support program enhances the effectiveness of smoking cessation medications.<sup>104</sup>

If a patient has failed initial treatment, has been intolerant of or refuses to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt. However, subjects should be informed that, although e-cigarette aerosol is likely to be much less toxic than cigarette smoking, the products are unregulated, contain toxic chemicals, and have not been proven as cessation devices. The patient should also be advised not to use the product indoors or around children because studies show that bystanders may be exposed to nicotine and other toxins (at levels much lower than cigarettes) through passive exposure to the e-cigarette aerosol. Because there are no long-term safety studies of e-cigarette use, patients should be urged to set a quit date for their e-cigarette use and not plan to use it indefinitely. It is also important to stress that patients should quit smoking cigarettes entirely as soon as possible because continued cigarette smoking, even at reduced levels, continues to impose tobacco-induced health risks (particularly for cardiovascular disease).

#### Tobacco Industry and Involvement

By 2013, the major tobacco companies had purchased or developed e-cigarette products (Table 3).

There is no evidence that the cigarette companies are acquiring or producing e-cigarettes as part of a strategy to phase out regular cigarettes, even though some claim to want to participate in “harm reduction.” Lorillard CEO Murray Kessler stated in an interview with the *Wall Street Journal* that e-cigarettes will provide smokers an unprecedented chance to reduce their risk from cigarettes.<sup>105</sup> He also published an op-ed in *USA Today* on September 23, 2013, stating: “E-cigarettes might be the most significant harm-reduction option ever made available to smokers.”<sup>106</sup> Shortly before this op-ed was published, however, Lorillard won approval from the US FDA to market new nonmentholated Newport conventional

**Table 3. Tobacco Companies That Have Acquired or Created E-Cigarette Companies and Brands (as of January 2014)**

| Tobacco Company          | Acquired E-Cigarette Company | E-Cigarette Brand(s) |
|--------------------------|------------------------------|----------------------|
| Altria Inc               | GreenSmoke                   | Mark Ten             |
| Reynolds American Inc    | No                           | Vuse                 |
| Lorillard                | Blu Cigs, Inc                | Blu                  |
| British American Tobacco | CN Creative                  | Vype                 |
| Imperial Tobacco         | Dragonite Holdings Ltd       | Ruyan                |
| Swisher                  | No                           | E-Swisher            |

E-cigarette indicates electronic cigarette.

cigarettes, expanding their cigarette line while touting their ability to offer a product they claim reduces harm from cigarettes. This allows the cigarette companies to have it both ways. (Likewise, after evaluating the cigarette companies' internal documents and public positions on snus [a form of moist snuff tobacco in a pouch popular in Sweden] as "harm reduction" in Europe, Gilmore et al<sup>107</sup> found that they were entering the snus market<sup>107</sup> and adopting "harm reduction" rhetoric<sup>108</sup> to protect their cigarette business as long as possible.) As noted in the 2010 Surgeon General's report,<sup>109</sup> the tobacco industry has used every iteration of cigarette design to undermine cessation and prevention.

The tobacco companies address e-cigarette issues as part of their policy agenda. As they did beginning in the 1980s,<sup>110,111</sup> they continue to engage in creating and supporting "smokers' rights" groups, seemingly independent groups that interact with consumers directly on political involvement in support of their agenda.<sup>111</sup> Altria and R.J. Reynolds Tobacco Company maintain Web sites called Citizens for Tobacco Rights and Transform Tobacco. E-cigarette news and action alerts are featured on the home pages of these websites and include instructions for taking action against bills designed to include e-cigarette use in smoke-free laws. E-cigarette companies engage in similar tactics, using the same political and public relations strategies as the tobacco companies (most notably featuring organized "vapers" like the organized smokers). They also use social media that is tightly integrated with their product marketing campaigns to press their policy agenda.<sup>22</sup> These strategies were successfully deployed in Europe to convince the European Parliament to substantially weaken the proposed EU Tobacco Product Directive in October 2013.<sup>112</sup>

#### Current State of Global Regulation (March 2014)

Like e-cigarette products, the policy environment related to e-cigarettes is rapidly developing despite the fact that the science is just emerging. Policy makers in many countries are under considerable pressure to provide regulatory guidance regarding e-cigarettes, often on the basis of the assumption that e-cigarettes will contribute to reducing the harms of smoking either by serving as a smoking cessation aid or by replacing combusted cigarettes. The data reviewed here, together with evidence of dual use and youth initiation of e-cigarette use, do not demonstrate any hypothesized harm-reducing effect.

Some countries (including Brazil, Singapore, Canada, the Seychelles, and Uruguay) have prohibited the sale of e-cigarettes, and many others are developing policies.<sup>1</sup> The United States, European Union, and United Kingdom illustrate the range of regulatory approaches being developed.

#### The United States

In the United States, as of March 2014, e-cigarette products remained unregulated by any federal authority, particularly the US FDA. The Sottera Inc case ruling that was upheld on appeal in the US court found that e-cigarettes could be regulated as tobacco products unless they are marketed with health and therapeutic claims.<sup>113</sup> The US FDA has stated its intent to assert ("deem") authority over e-cigarettes but has yet to act. The US FDA does not have the authority to regulate where e-cigarettes are used; that is the domain of state and local governments, where almost all activity on smoke-free laws has occurred.

Since e-cigarettes entered the US market in 2008, there has been a rapid increase in the number of municipalities and states that have adopted legislation regulating where e-cigarettes can be used and laws restricting sales to minors. As of March 2014, 27 states had laws restricting sales to minors, 1 state (Minnesota) taxed e-cigarettes as tobacco products, and 3 states (New Jersey, North Dakota, and Utah) and >100 municipalities (including New York, Los Angeles, San Francisco, and Chicago) prohibited the use of e-cigarettes in 100% smoke-free indoor environments.<sup>114</sup> An additional 9 states restricted e-cigarettes in other venues such as school district property, Department of Corrections/prisons, public educational facilities and grounds, and commuter transit systems.<sup>114</sup> Some local and statewide smoke-free laws enacted before the introduction of e-cigarettes include language that could be interpreted as including e-cigarettes.

#### European Union Tobacco Product Directive

In February 2014, the European Parliament approved a revised European Union Tobacco Product Directive that regulates e-cigarettes with nicotine concentrations up to 20 mg/mL (an amount equal to that in a pack of cigarettes) as tobacco products.<sup>115</sup> E-cigarettes with higher nicotine concentrations or intended therapeutic uses will be regulated as medical devices.<sup>116</sup> The directive stipulates that e-cigarettes must be childproof and that packaging must include information about ingredients, adverse effects, and health warnings.<sup>115</sup> Refillable cartridges are allowed as long as their volume does not exceed 2 mL (but could be banned by the European Commission if at least 3 member states prohibit them on the basis of risks to human health).<sup>115</sup> Marketing and advertising restrictions will mirror those of tobacco products.<sup>115</sup>

#### The United Kingdom

In the United Kingdom, the Medicines and Healthcare Products Regulatory Agency announced a plan to regulate e-cigarettes as medicines on the basis of the assumption that e-cigarettes function like NRTs for smokers wishing to cut down or quit.<sup>78</sup> As of January 2014, Medicines and Healthcare Products Regulatory Agency policies did not include any restrictions on e-cigarette marketing.<sup>117</sup> The antismoking advocacy group Action on Smoking and Health UK has announced that it "does not

consider it appropriate to include e-cigarettes under smokefree regulations,<sup>118</sup> supporting one of the e-cigarette companies' key marketing messages that e-cigarettes can be used everywhere without the restrictions and social stigma of smoking.<sup>3,119</sup>

### Policy Recommendations

E-cigarettes deliver lower levels of some of the toxins found in cigarette smoke. Main concerns about the potential of e-cigarettes to make a contribution to reducing the harm caused by cigarette smoking arise from effects on youth, dual use with cigarettes resulting in delayed or deferred quitting (among both adults and youth), and renormalization of smoking behavior.

The ultimate effect of e-cigarettes on public health will depend on what happens in the policy environment. These policies should be implemented to protect public health:

- Prohibit the use of e-cigarettes anywhere that use of conventional cigarettes is prohibited.
- Prohibit the sale of e-cigarettes to anyone who cannot legally buy cigarettes or in any venues where sale of conventional cigarettes is prohibited.
- Subject e-cigarette marketing to the same level of restrictions that apply to conventional cigarettes (including no television or radio advertising).
- Prohibit cobranding e-cigarettes with cigarettes or marketing in a way that promotes dual use.
- Prohibit the use of characterizing flavors in e-cigarettes, particularly candy and alcohol flavors.
- Prohibit claims that e-cigarettes are effective smoking cessation aids until e-cigarette manufacturers and companies provide sufficient evidence that e-cigarettes can be used effectively for smoking cessation.
- Prohibit any health claims for e-cigarette products until and unless approved by regulatory agencies to scientific and regulatory standards.
- Establish standards for regulating product ingredients and functioning.

In addition to being important in their own right, should these policies be put in place together with policies designed to make combustible tobacco products (eg, cigarettes, cigars, cigarillos) less desirable and available, it is possible that current conventional cigarette smokers who will not quit nicotine would shift to e-cigarettes without major dual use or youth initiation to nicotine addiction with e-cigarettes. Absent this change in the policy environment, it is reasonable to assume that the behavior patterns that have been observed for e-cigarettes will persist, which makes it unlikely that they will contribute to reducing the harm of tobacco use and could increase harm by perpetuating the life of conventional cigarettes.

### Conclusions

Although most of the discussion of e-cigarettes among health authorities has concentrated on the product itself, its potential toxicity, and use of e-cigarettes to help people quit smoking, the e-cigarette companies have been rapidly expanding using aggressive marketing messages similar to those used to promote cigarettes in the 1950s and 1960s. E-cigarette advertising is on

television and radio in many countries that have long banned similar advertising for cigarettes and other tobacco products and may be indirectly promoting smoking conventional cigarettes. Although it is reasonable to assume that, if existing smokers switched completely from conventional cigarettes (with no other changes in use patterns) to e-cigarettes, there would be a lower disease burden caused by nicotine addiction, the evidence available at this time, although limited, points to high levels of dual use of e-cigarettes with conventional cigarettes, no proven cessation benefits, and rapidly increasing youth initiation with e-cigarettes. Although some cite a desire to quit smoking by using the e-cigarette, other common reasons for using the products are to circumvent smoke-free laws and to cut down on conventional cigarettes, which may reinforce dual use patterns and delay or deter quitting.

The trajectory of the dual use pattern among adults or children is unclear, but studies of youth find that as many as one third of youth who use e-cigarettes have never smoked a conventional cigarette. Nicotine is a highly addictive substance with negative effects on animal and human brain development, which is still ongoing in adolescence.<sup>120-123</sup> Furthermore, high rates of dual use may result in greater total public health burden and possibly increased individual risk if a smoker maintains an even low-level tobacco cigarette addiction for many years instead of quitting.

Although data are limited, it is clear that e-cigarette emissions are not merely "harmless water vapor," as is frequently claimed, and can be a source of indoor air pollution. Smoke-free policies protect nonsmokers from exposure to toxins and encourage smoking cessation.<sup>124</sup> One hundred percent smoke-free policies have larger effects on consumption and smoking prevalence,<sup>125</sup> as well as hospital admissions for myocardial infarction, stroke, and other cardiovascular and pulmonary emergencies,<sup>126</sup> than weaker policies. Introducing e-cigarettes into clean air environments may result in population harm if use of the product reinforces the act of smoking as socially acceptable or if use undermines the benefits of smoke-free policies.

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Dr Benowitz is a consultant to several pharmaceutical companies that market smoking cessation medications and has been a paid expert witness in litigation against tobacco companies. Drs Grana and Glantz report no conflicts.

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KEY WORDS: adolescent ■ particulate matter ■ public policy ■ smoking

Senator BOXER. And here's the deal, it's pretty well peer-reviewed. They say, "Health claims and claims of efficacy for quitting smoking are unsupported by the scientific evidence to date."

And these are leading scientists. So, Mr. Myers, you ought to get a look at this too. Because, I don't think you were accurate in your response either. I need to go on. I don't have time. And I have to make some points here.

Now, my two friends from these e-cigarette companies, you believe, I'm sure, that nicotine is dangerous to adolescents. Is that correct?

Mr. WEISS. Yes, I do.

Senator BOXER. Do you?

Mr. HEALEY. Correct.

Senator BOXER. OK.

And you're aware that the U.S. Surgeon General said "nicotine exposure during adolescence may have lasting adverse consequences for brain development and adolescents are particularly vulnerable to this highly addictive drug."

So I am just asking you, because you said that you are working to get adults off cigarettes. That's your goal and that's your mission in your companies. Have you ever had a conversation in your company, informally, formally, with another executive, about how this product could be marketed to non-smokers?

Mr. HEALEY. I can say I haven't had that conversation.

Senator BOXER. Did anyone in your company ever have that conversation—

Mr. HEALEY. Not that I'm aware of, Senator.

Senator BOXER.—marketing to non-smokers? Not that you're aware.

What about you, Mr. Weiss?

Mr. WEISS. Absolutely not.

Senator BOXER. OK.

What's in your cigarettes? Tell me what's in them?

Mr. WEISS. There's nicotine, propylene glycol, glycerin and flavorings.

Senator BOXER. OK. How about yours?

Mr. HEALEY. The same with nicotine and distilled water to that list.

Senator BOXER. OK.

Are you aware that there were some formaldehyde found in these cigarettes?

Mr. WEISS. Yes.

We've tested our products and there's no formaldehyde in the ingredients of our products.

Senator BOXER. How often do you test your products?

Mr. WEISS. We test them pretty frequently.

Senator BOXER. And so, this story that found formaldehyde had nothing to do with your two companies?

Sir? Mr. Healey?

Mr. HEALEY. Not for mine, Senator. No.

Senator BOXER. And not for yours? No, they didn't find any—the *New York Times* story?

Mr. WEISS. No.

*The New York Times* was not testing our products; no.

Senator BOXER. Now, it's unequivocal that you do not market to kids. So here's my question to Mr. Healey. You sell your products in cherry crush and vanilla flavors. Cherry crush. Yet, your parent company has a youth smoking prevention website, your parent company, that says "Kids may be vulnerable to try e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, piña colada, and berry." You sell cigarettes in three of those flavors. How can you sit here and say you're not marketing to children?

[The information referred to follows:]



Mr. HEALEY. Senator, it's a good question. And flavors——

Senator BOXER. What's the answer?

Mr. HEALEY. The answer is the average age of a "cherry" smoker is in the high 40s but also we found that flavors increase, or sorry, decrease the ability or possibility of adult smokers to use e-cigs switching back because they don't want——

Senator BOXER. Why—whoa, whoa, whoa!

Why did your parent company, in their youth smoking prevention website, say "Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, piña colada and berry?" And you sell them in three of the flavors. Are you marketing to children?

Mr. HEALEY. No, I am not.

Senator BOXER. So who is attracted to cherry, berry, vanilla? Who is attracted to that? Adults?

Mr. HEALEY. Adult smokers, yes.

Senator BOXER. They are. That's interesting.

And I would like to say to Mr.—even though your parent company called you out on it?

Mr. WEISS, your company previously committed to not sell e-cigarettes in flavors. Now, Wall Street investors report you're going to be offering 10 new flavors and more to come. What are these flavors? Can you mention them?

Mr. WEISS. Sure.

There are a variety of flavors but pomegranate is one. We have adult flavors like single-malt scotch, for an example. I would say that—

Senator BOXER. You have adult flavors as opposed to your kid's flavors?

Mr. WEISS. Well, for example, we're not offering cotton candy or Gummy Bears.

Senator BOXER. Oh, wonderful.

What are you offering? What are on the list of your ten? Do you have them there?

Mr. WEISS. I don't have it listed here. I could probably remember them off the top of my head.

Senator BOXER. Go ahead.

Mr. WEISS. And so, in addition, there's vanilla bean, there is also a peach tea, there's also—

Senator BOXER. Sir, since I don't have time because my time is very limited, would you make that available before the end of the day?

Mr. WEISS. Yes, no, of course.

Senator BOXER. OK.

And I wanted to show the flavors that we see in e-cigarettes. I don't know the flavors Mr. Weiss is now coming up with since he said before he wasn't going to, but I'm just going to ask our advocacy people here; the two at the end.

You think cotton candy is something that's attractive to children or adults?

Dr. TANSKI. I would argue that cotton candy would be attractive to children.

Senator BOXER. What about Gummy Bears, Mr. Myers?

Mr. MYERS. I would agree and the evidence shows that to be the case.

Senator BOXER. And then Popsicle. OK.

So for e-cigarettes as an industry, to proclaim that they're not advertising to kids and they're choosing these flavors, and we don't know yet Mr. Weiss' flavors, and we now heard that cherry and berry, even though your parent company said that they attracted kids, you don't think they attract kids.

You're wrong. You're wrong.

And let's look at some of the advertisements.

Could somebody help us? Thank you.

These are cartoons. They're not by your companies; other companies. I want to say to my children's advocacy people, do those look like they're aimed at children or adults?

Dr. TANSKI. Senator Boxer, I would agree that those—that would be Papa Smurf and that would look like it would be appealing to children as there are movies that are featuring the Smurfs.

Senator BOXER. And, as a grandma, I could attest the fact that the biggest movie now is *Frozen*, and then the biggest song is “Let It Go.” And one of the e-cigarettes has their logo “Let It Glow.”

Now, I am saying to my Chairman, whom I adore, whether it’s his birthday or not his birthday, on every day I share his views on this. And I’m asking Mr. Weiss and Mr. Healey to look into your heart. You can sit and say whatever you want. You can con yourself into thinking what you know.

We don’t know if this product gets people off cigarettes yet. It’s not proven, number one. So don’t think that you’re doing some great mission. And then, don’t say that you really care about kids when you go against your own parent company’s advice and start using these flavors. I have some of these flavors here. I’m not supposed to touch them because they’re like poison; seriously.

What is this one? Pink Spot. Gummy Bear Pink Spot. Rocket pop. Cotton candy.

We are seeing a repeat and we, here in this committee, get it. And I’m just saying, I have a lot of other questions I’ll forward for the record, but I think all of this is very important. And I know the people in the industry. You can talk yourselves into everything.

When I was a young woman, doctors said “Smoke a cigarette, it will calm you down.”

Thank God my mother said “Not on your life.”

Don’t be a part of this because you’ll regret it.

The CHAIRMAN. Thank you, Senator Boxer.

Senator Blumenthal.

**STATEMENT OF HON. RICHARD BLUMENTHAL,  
U.S. SENATOR FROM CONNECTICUT**

Senator BLUMENTHAL. Thanks, Mr. Chairman.

And, like the previous colleague, I am tremendously respectful. I’m not going to go quite so far as saying I’m adoring, but we love you and happy birthday.

The CHAIRMAN. You’d like my daughter too.

Senator BLUMENTHAL. Your daughter is great.

The CHAIRMAN. One of your constituents.

Senator BLUMENTHAL. Like all of our children, they are better generation to generation.

But I also want to thank your staff and our staff for the excellent work they have done in putting together this really profoundly important hearing and it does have a very eerie and haunting feel. The only difference between your testimony today and the testimony that tobacco executives is that you’re not under oath because I find in this testimony a sense of denial that I cannot creditable accept. And the reason is that it’s defied by the numbers. The latest report by the Legacy Foundation shows that 18 million teens were exposed to blu’s print and TV ads within a 6 month period, alone. It shows that NJOY’s ads reached 3 million teens.

There’s a legal principle that people are responsible for the natural and logical effects of what they do because they know those effects. And you know that you’re reaching children and teenagers.

So I think we have seen this movie before, it's called "big nicotine comes to children near you." And you are using the same kind of tactics and promotions and ads that were used by "Big Tobacco" and proven so effective.

I want to show you, for example, one, to begin with if we can show it. You can see our old friend, Joe Camel, and our new friend who is Mr. Kool.

[The picture referred to follows:]



Senator BLUMENTHAL. Anybody recognize Mr. Kool?

Mr. HEALEY. I do, Senator.

Senator BLUMENTHAL. Yes.

Are you here denying that Mr. Kool appeals to teenagers and children?

Mr. HEALEY. Mr. Senator, that particular illustration was not a commercial. It was placed on our website for our consumers as an education piece. Now, I understand you—

Senator BLUMENTHAL. It was an education piece on your website.

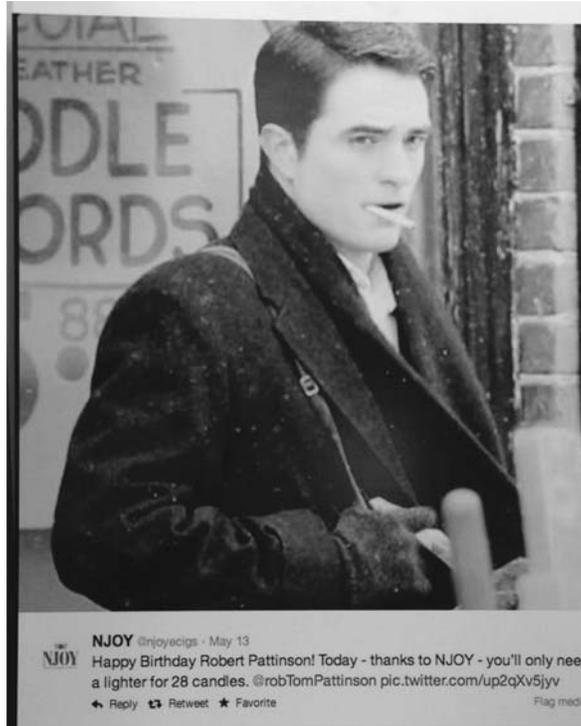
Mr. HEALEY. Yes, sir.

Senator BLUMENTHAL. So it was not in any way designed to represent your company? Is that your testimony? Are you denying that it represents an official act of your company?

Mr. HEALEY. No.

What I'm saying is that it wasn't a commercial. It had education pieces that were specifically aimed at our consumers. Now, we have taken it down because when I had objections and people said to me "I think this is inappropriate." Well, I disagreed that the messaging wasn't aimed at children—

Senator BLUMENTHAL.—inappropriate but the tactics that you substituted are equally so. You're one step ahead of your critics. Let's look at the next visual; if we may.  
[The picture referred to follows:]



Senator BLUMENTHAL. Now, anybody recognize him?  
Mr. WEISS?  
Mr. WEISS. Yes.  
Senator BLUMENTHAL. Who is he?  
Mr. WEISS. I believe that's Robert Pattinson.  
Senator BLUMENTHAL. And what does he have in his mouth?  
Mr. WEISS. NJOY electronic cigarette.  
Senator BLUMENTHAL. Your product.  
Mr. WEISS. Correct.  
Senator BLUMENTHAL. He looks a lot like Mr. Cool; doesn't he?  
Mr. WEISS. He's an adult smoker.  
Senator BLUMENTHAL. Well, he's an adult smoker but do you deny in your testimony today that this ad that the use of this image, it's designed to appeal to children and teenagers?  
Mr. WEISS. I do.  
Senator BLUMENTHAL. Why?  
Mr. WEISS. Because he's a 28-year-old adult smoker.  
Senator BLUMENTHAL. So your testimony is that adult role models have no appeal to children or teenagers? In other words, if they're older than 18, they have no impact on people under 18? Is that what you're saying?

Mr. WEISS. What I'm saying is that our target is to reach adult smokers and being able for adult smokers to see other adult smokers that perhaps that they admire that are using an alternative to a toxic cigarette; that that's a good thing.

Senator BLUMENTHAL. Well, these ads and these images are designed to appeal to children. Well, again, they are not only reminiscent, they're really duplicative in my view of the tactics adopted by Big Tobacco. You've taken their playbook and you've modified it to a non-combustible nicotine delivery mechanism. And this hearing is not so much about the contents of e-cigarettes or their potential health effects, which I find somewhat difficult to accept on the evidence we have so far, it's about the marketing and promotion tactic. The use of several celebrities like Robert Pattinson and images like Mr. Kool and others that I hope perhaps we can reach on a second round of questioning, but in my view the evidence is undeniable that you are seeking not only to renormalize, but in fact, to re-glamorize tobacco use. And that these products for many, many children and teenagers will be a clear path and gateway to combustible tobacco use, otherwise known as cigarettes.

My time has expired. I apologize, Mr. Chairman. And I hope that on a second round we can hear more responses.

The CHAIRMAN. You've been doing this a long time, Senator Blumenthal.

Senator Klobuchar.

**STATEMENT OF HON. AMY KLOBUCHAR,  
U.S. SENATOR FROM MINNESOTA**

Senator KLOBUCHAR. Thank you very much, Chairman Rockefeller.

I'm a former prosecutor and I like to look at the facts here. And the first fact that Senator Blumenthal mentioned that really sticks out to me is that a recent study found that almost 2 million kids have tried these e-cigarettes. That's a problem right there.

And I look at—

Will you put that picture back up there of the Twilight guy, Pattinson?

OK. So have you gone to those movies, Mr. Weiss?

Mr. WEISS. Yes. I have.

Senator KLOBUCHAR. OK.

Have you been in those theaters? Because, I have with my daughter when she was 16. And, I can tell you that the people in those theaters, for the most part, are kids. And the people that read those books, for the most part, are girls. And I have seen this many times because I've had to be up at two in the morning when they do the premier and all the girls go to see the movie.

And this is a birthday, happy birthday to Robert Pattinson. I noticed the, Senator Blumenthal, he is here.

Do you think that really appeals to me or Senator Blumenthal, to wish him happy birthday?

Mr. WEISS. Again, I'll just repeat what I said earlier, that he's an adult smoker. We're trying to appeal to adult smokers.

Senator KLOBUCHAR. OK. He's an adult in movies that appeal to kids. And that's what matters to me because this is a marketing technique.

And the third fact that I wanted to move to is the flavoring issue. And I don't understand why when regular cigarettes, they can't have flavors; right? Is that correct? They've been banned from having flavors?

Mr. WEISS. Right.

Senator KLOBUCHAR. I guess I'd ask you, Mr. Myers or Dr.—why were they banned from having flavors for regular cigarettes?

Mr. MYERS. They were banned because Congress determined, after substantial evidence, that they mostly appeal to young people.

Senator KLOBUCHAR. Right, exactly.

And so, I don't understand why you couldn't have your product without flavors?

Mr. Weiss?

Mr. WEISS. So, for us, we view every decision that we make through the lens of what is going to help accomplish our mission to obsolete cigarettes. And so, because we're only interested in adult smokers, we had not yet sold any products that contained any flavors. And still, as of today, don't. So as a responsible company, prior to offering flavors, we actually conducted research to ensure that, to the greatest degree possible, we would not appeal to non-smoking youth with the flavors that we would provide.

And so, we're trying to understand who uses our product with the goal of appealing to adult smokers without appealing to minors. And we were satisfied with the results of that research which we would be happy to submit for the record. The research was conducted by Saul Shiffman, who is actually present here today and is willing to answer questions to you or your staff.

Senator KLOBUCHAR. I got to tell you, just having an 18 year old, just because they have alcohol names on them, they think those things are cool. I know, I think it was you Mr. Healey, that had the piña colada brand. I think a lot of youth think those are cool.

Not to mention the ones that Senator Boxer mentioned, those flavors. And I just think any flavors of something that kids like. The other thing, forth fact, I wanted to follow up on is the Mr. Kool ad that you said was just on a website, was that right?

Mr. HEALEY. Correct.

It was in an ad placed in——

Senator KLOBUCHAR. OK.

So let's talk about the website. And I understand that a lot in the social media and how a lot of this is. And I understand the study out this month shows that e-cigarettes are being heavily marketed on Twitter. Over a two-month period there were 70,000 tweets related to e-cigarettes. Nearly 90 percent of the tweets were from e-cigarette companies, and almost all of these included a website link.

Now, I also understand that when people sign up for the Twitter account, they have to say they're over 18. Is that right or 18 or over; over 18?

Mr. HEALEY. Yes.

The social media sites have age verification or certification processes that we install.

Senator KLOBUCHAR. OK, but they're public tweets. So anyone can get on these Twitter accounts. And anyone can get on YouTube; right? None of the videos are age restricted; is that right?

Mr. HEALEY. Correct.

Senator KLOBUCHAR. So I would just think, I just got to tell you that my in-laws use, I don't think they use Twitter. They're in their 70s, but I know that all of my daughter's friends use Twitter and they all use Facebook and they're very adept on social media that is putting it in a minor fashion. And so, I would think that this kind of marketing would be particularly appealing to kids. And I wondered if you wanted to comment on that, Dr. Tanski?

Dr. TANSKI. I think you're completely correct that using social media is a particularly adept way of reaching young people. And to the point of the age restrictions, the websites for electronic cigarettes, to my knowledge right now, most of them say "Are you over 18?" And you say "Yes" and you're in rather than having the double forms of age verification that they do, say, on some of the combusted tobacco websites. It's far easier to just say yes and you can get right in.

So I agree that the protections to youth are relatively weak to be able to have access to some of this social marketing. And it's very powerful, as you noted.

Senator KLOBUCHAR. OK.

Mr. Myers?

Mr. MYERS. I completely agree.

It isn't 70-year-olds who are looking at Twitter or the YouTube videos that are out there. And we, too, look at the age verification on the e-cigarette sites, including Lorillard's, and it is nowhere near comparable to what is the set of the requirements for cigarettes. So it's a dual standard; one allows young people and much, much easier.

Senator KLOBUCHAR. OK.

I just want to conclude in my closing argument, as a former prosecutor, so what you have here are 2 million kids and growing; you've got marketing of flavors, which we know from the past with regular cigarettes, that is the very reason why we banned flavorings in regular cigarettes and now you have this happening again like *Groundhog Day*; and then the third thing that we know is that we've got a heavy use of social media, which we also know is targeted to youth. It's a great way to reach youth; in fact, one of the only ways to reach youth at times if you got any kid that's on their iPhone constantly and texting, looking at things.

And then we've got our, sort of, celebrity models, which I got to tell you about—most people over 50 are not going to know who Robert Pattinson is as much as you like to think it. And just that he's 28 years old and has 28 candles; Justin Bieber is over 18 too. And if so, and put an ad out for him. You probably wouldn't do that, by the way. But if someone put him up there, even though he's over 18 years old, I don't think that anyone is going to think that is marketed adults.

So this is my exhibit. So thank you very much. I just think that, to me, when you look at all these facts, there is heavy-duty marketing going on to youth. And the last thing we need, as to them, get dependent when we've just started to see such success.

Thank you.

The CHAIRMAN. I'm going to sneak a question in before Senator Nelson.

Mr. Healey, you said that you're a smoker?

Mr. HEALEY. Yes, Chairman.

The CHAIRMAN. How many years have you been a smoker?

Mr. HEALEY. I started at 23 and I'm 40 and two months. I'm not good at math, but a fair amount of time.

The CHAIRMAN. And you're using e-cigarettes to help you get rid of your cigarette—I'd like to hear about it's working; how long have you been doing it; what do you notice?

Mr. HEALEY. To be honest—

The CHAIRMAN. I think what you're, from Mr. Myers over, I think you're all talking into the clouds in terms of facts. You're disingenuously trying to say something which you should not be saying. But to your credit, you're trying to get off of tobacco, and so how is the e-cigarette helping you do that?

Mr. HEALEY.—I can only speak to my personal story. I was smoking a pack and a half of cigarettes a day. Now, at best, I will smoke five tobacco cigarettes a week; a lot of times, none. And it makes it very difficult, for me as an e-cig smoker, that wasn't my intent, necessarily, but being that it doesn't taste and remind you of tobacco, it's difficult to go back to tobacco as consistently as you were.

The CHAIRMAN. All right.

One other question: Does Lorillard allow distributing of free samples to kids?

Mr. HEALEY. blu distributes—

The CHAIRMAN. So that means blu.

Mr. HEALEY. Yes—samples to verified 18 or above smokers.

The CHAIRMAN. And, how do you know that they're 18 or above?

Mr. HEALEY. We have machines that they have to provide, first, provide their Driver's License, State Driver's License. It's swiped to be verified and then the first question they're asked is: Are they a smoker? If they say no, their experience with us ends. If they say yes, we talk to them about the product and then they can acquire a sample.

The CHAIRMAN. So you think that's a virtuous civic duty that you're performing there?

Mr. HEALEY. I think we should be responsible, particularly when handing the product to someone.

The CHAIRMAN. Senator Nelson.

**STATEMENT OF HON. BILL NELSON,  
U.S. SENATOR FROM FLORIDA**

Senator NELSON. Mr. Chairman, as usual, you have picked a hearing on an important topic of the day. So thank you very much.

I want ask Dr. Tanski, you testified that there was a recent increase of nicotine poisoning cases in young children. Are these cases mainly coming from children getting into the refill vials of liquid nicotine or are you seeing the poisoning cases from the disposable e-cigarettes?

Dr. TANSKI. Unfortunately, Senator, we don't actually have that level of detail. What we know is that the trajectory of the number of calls has been increasing for electronic cigarette and nicotine devices very rapidly with 251 calls in just the month of February. We don't have the kind of detail that say if they're coming from the re-

fill devices or not. My personal suspicion is that's the greatest likelihood for the kids to get into them rather than the whole cigarettes, themselves; the whole electronic cigarettes themselves.

Senator NELSON. You also note that there are currently now standards for governing childproof packaging for these liquid nicotine bottles. And I would like, Mr. Chairman, if this has not already been entered into a record, it's a photograph of a number of these liquid flavors: Banana Split, Cotton Candy, Kool-Aid Grape, Skittles, Sweet Tart, Gummy Bear, Fruity Loops, Rocket Pop, Hawaiian Punch.

Doctor, would you support giving either the Consumer Product Safety Commission or the FDA express authority to enforce childproof packaging for toxic or harmful household substances on all of those liquid nicotine containers?

Dr. TANSKI. Absolutely, Senator.

It is critically important that we protect youth and children especially from these nicotine containing products. Everything else in your home that is toxic pretty much has a child safety cap on it; whether it's a bottle of bleach or the medications that you take home from the pharmacy. They're all contained in something that is harder to get into so that it gives that extra time so a parent can be there so that they don't have a toxic exposure.

So I ask for your help. We believe that the FDA has regulatory authority over the packaging, although it's not yet been commented on, and I would encourage you guys as a committee to please help us. I think the Consumer Product Safety Commission should consider, if possible, to include their oversight to include this as a toxic product. I know that at present tobacco products are excluded from the packaging regulations, but perhaps that should be revisited and this should be considered somehow different from other tobacco products.

Senator NELSON. Maybe all the more needed, the Gummy Bear actually has a picture of Gummy Bears on the label.

[The information referred to follows:]



Senator NELSON. Mr. Weiss, you have stated that there should not be restrictions on responsible advertising of e-cigarettes or other types of these nicotine vapor products. Tell us what is responsible. And what is your responsible advertising in your industry?

Mr. WEISS. Responsible advertising is trying to reach the more than 40 million adult smokers in this country over almost 500,000 of who die every year prematurely from tobacco-related illness. Trying to reach those people and get them off of the toxic products that they're currently using is a responsible thing to do.

Irresponsible, I think, would be the use of cartoon characters or images trying to target children with advertising during television programming that appeals to children; things of that sort.

Senator NELSON. Well, is it responsible to show an e-cigarette that looks almost exactly like a combustion cigarette in a television ad? Is that responsible?

Mr. WEISS. I believe that it is because I think for most smokers, if you asked what an electronic cigarette is, they think it's a very complicated device with a lot of wires and it was important for us to communicate to them that it could be as close as possible to the product they are currently using and that would make it as easy as possible for them to transition from one habit, which is unfortunately a habit that is going to prematurely end their life, to another habit we felt had the potential for reduced harm.

Senator NELSON. For an adult who knew all of that, but what about for a kid that's looking at that TV advertisement? Doesn't the message send to that kid that doesn't know the sophistication of what you just said that it's okay to have either one?

Mr. WEISS. No.

That's why we have in our messaging, for example, "friends don't let friends smoke," which was our ad campaign that we did earlier this year. That's the kind of ad campaign that I think the public health community should support.

Senator NELSON. I think that's where you're going to run into some problems. In the public sector, we've been through this with tobacco in children; we have seen how tobacco companies have tried to hook children through these seductive advertisements on nicotine because once they get them as a child it's going to be tough all through their life as an adult to get off of it. And I think you are going to have some significant pushback on blending and blurring the two.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Nelson.

Senator Markey, would you forgive me if the power structure of the—

[Laughter.]

The CHAIRMAN. I was actually—

[Laughter.]

The CHAIRMAN. No, the power structure is here with coffee. And black coffee, no sugar. And we were actually going to give a presentation before all of this started, but because these are the power structures, he was doing something that required the use of power.

So would you yield for a moment to Senator—

Senator MARKEY. I think that—

Senator BLUMENTHAL. You have a right to remain silent.  
[Laughter.]

Senator MARKEY. I spoke on the Durbin Amendment on the House floor in 1987, I think it was, which was the first amendment ever brought out on the House or Senate floor to ban smoking on flights 2 hours or less. And that amendment passed by a vote. And so, we're here with a historic figure on this issue with Durbin. So I'll be more than willing to hear, I'm sure a historic presentation. So—

The CHAIRMAN. Yes. You just begin.

**STATEMENT OF HON. RICHARD J. DURBIN,  
U.S. SENATOR FROM ILLINOIS**

Senator DURBIN. I want to thank the Chairman for his kind remarks and also my colleagues. And thank you for your patience.

And I'm going to submit my statement for the record.  
[The prepared statement of Senator Durbin follows:]

PREPARED STATEMENT OF HON. RICHARD J. DURBIN, U.S. SENATOR FROM ILLINOIS

I commend Chairman Rockefeller and Senator Thune for their leadership in convening this hearing, and I thank Chairman Rockefeller for inviting me to participate.

Although we have cut smoking rates in this country by half, today, we face a new threat—the rise of e-cigarettes. Thanks to the exploitation of loopholes and insufficient action by the FDA, e-cigarettes are being marketed to children today just as cigarettes were 50 years ago.

What's worse, these marketing techniques are just as effective in reaching today's youth as they were then.

**Extent of the Threat**

E-cigarette use among our Nation's children is on the rise. The Centers for Disease Control and Prevention released data last year showing that, in just one year—from 2011 to 2012—the percentage of middle and high school students who had used e-cigarettes more than doubled. This same study found that one in five middle school students who reported using e-cigarettes had never tried conventional cigarettes. This suggests that, among young people, e-cigarettes could be a gateway to nicotine addiction and smoking.

A new study released in *JAMA Pediatrics* goes even further. This study found that middle and high-school students who used e-cigarettes were more likely to smoke traditional cigarettes and less likely to quit smoking. In fact, according to the 2014 Surgeon General's report, many kids and young adults who are occasional smokers go on to become daily smokers—2,100 of them every day.

For tobacco companies, the case for targeting young people is simple. Nearly 90 percent of adult smokers began smoking before they graduated from high school. Given how addictive nicotine is, almost all of those high school kids become a customer for life for tobacco companies.

But, the human and financial toll is devastating. If current smoking trends continue, 5.6 million American kids will die prematurely from a smoking-related illness.

**Potentially Harmful Chemicals**

E-cigarette manufacturers often claim their products actually provide some public health benefit. E-cigarette manufacturer Lead by Sales, which markets for White Cloud brands, states, "You get the feeling of smoking real cigarettes without all of their negative side effects."

There is little to no evidence to support these claims. Further, emerging evidence published in *JAMA Internal Medicine* suggests that e-cigarettes *don't* help people quit or reduce overall cigarette consumption.

The CDC data and *JAMA Pediatrics* article suggest that e-cigarettes may actually serve as a gateway to traditional cigarettes, especially among children.

There's another problem with this claim that there may be a health benefit. We don't know what is in these products because they are not currently regulated. Some early studies show that vapors generated by e-cigarettes contain toxins, including

formaldehyde—a known carcinogen—and acetaldehyde—a potential carcinogen—and metals, such as cadmium, nickel, and lead.

Nicotine itself also poses serious harms. The number of calls to poison control centers involving e-cigarette liquids with nicotine has skyrocketed. In September 2010, there was one call involving e-cigarette liquid. In February 2014, there were 215.

More than half of these calls involved children under age 5. Babies, really. Let me tell you about one of these cases. Last summer, in Illinois, a four year-old child got into a vial of Juicy Vapor e-liquid, and swallowed a small amount. The child vomited and became ashen and lethargic. He was rushed to the local Emergency Department, and luckily, after several hours, he was released from the hospital.

### **Tobacco Industry Tactics**

Unlike regular tobacco, e-cigarette companies are legally allowed to market their products in ways that reach millions of children. In April, ten of my Congressional colleagues and I released a report documenting how leading e-cigarette manufacturers are marketing e-cigarettes to our young people.

The industry is using longstanding advertising techniques that they know are effective, because they used the same techniques to hook previous generations of smokers. We found that many of these companies hired glamorous celebrities to push their brands through TV and radio ads. They sponsored events with heavy social media promotion. They even revived cartoon characters, in a way that calls to mind Joe Camel—the deadliest cartoon of the 20th century.

Lorillard, as you may recall, was among the seven companies that testified before a House Committee 30 years ago, arguing that cigarettes were not addictive. Now Lorillard is back, arguing that they don't market to kids.

A robust analysis recently published in the journal *Pediatrics* suggests otherwise. Between 2011 and 2013, exposure to e-cigarette marketing by children aged 12 to 17 rose 256 percent. 24 million children saw these ads. Lorillard's Blu e-cigarette accounted for 80 percent of this advertising targeted at 12 to 17 year-olds.

And these tactics seem to be working. A parent was presenting to a group of 5th grade students in Massachusetts the harmful effects of smoking. To the parent's dismay, the students—and I mean all 22 of the students, even the presenter's daughter—were adamant that the “‘water vapor’ cigarettes” were fine.

And some kids said that they were just like candy cigarettes, with flavors like bubble gum. When the teacher described how these e-cigarettes were harmful, the kids were insistent she was wrong.

Perhaps this is why e-cigarette companies have dramatically increased their spending on marketing—in 2013 alone, the six companies in our investigation spent \$59.3 million to advertise their e-cigarette products. Lorillard alone increased its advertising budget for Blu from \$2 million in 2011 to more than \$40 million in 2013.

But they don't stop there. Not only is the marketing and packaging intended to appeal to young people, so is the product itself. Let me read you a list of e-cigarette flavors being marketed by some of the people here today—vivid vanilla, piña colada, chocolate treat, and cherry crush. The manufacturer VMR boasts over 42 e-cigarette flavors.

The Family Smoking Prevention and Tobacco Control Act bans flavored cigarettes largely because of their disproportionate appeal to kids. Why would we allow the tobacco industry to use this tactic again to lure in a new generation of tobacco users?

### **Steps to Effectively Regulate Tobacco**

On June 22, we will celebrate the 5th anniversary of the Family Smoking Prevention and Tobacco Control Act. After years of waiting, the FDA finally began to issue its regulations on e-cigarettes and other tobacco products not covered by the Tobacco Control Act. The FDA should not extend the comment period on these regulations, which would delay the process even further.

FDA proposes to ban direct sales to minors and to require these companies to list their ingredients. But the FDA's regulations were dangerously silent on one of the most pressing questions of all—the marketing of these addictive products.

Fifty years from now—in 2064, at the 100th anniversary of the Surgeon General's report—I hope we can look back and not wish that we had acted more quickly as the threat of e-cigarettes became apparent. If the FDA takes decisive action now, it can spare the next two generations from years of suffering and lethal struggle against nicotine addiction that have brought so much loss and heartbreak since 1964.

Senator DURBIN. And first, acknowledge the presence of Matt Myers. Matt and I have been in this struggle for a long time trying to save and spare kids from tobacco and what it does to them.

And we know when addiction starts. They start in your adolescence. If you can sell an addictive product to an adolescent, you got them. You may have them for life. And that's why a lot of marketing is done for children.

Back in the day, it was just bold-faced marketing; Joe Camel and everything you can imagine. And the kids were wearing t-shirts and hats and, sadly, becoming addicted to products that would absolutely be the end of their healthy lives if they weren't careful.

And now, we have this argument by the e-cigarette industry that it's just an accident that all your advertising and marketing is appealing to so many kids. That's a little hard to understand. I think it's hard to believe. Look at the numbers here. E-cigarette use among nation's kids is on the rise. CDC released the end of last year showing in 1 year, from 2011 to 2012, the percentage of middle and high school student who used e-cigarettes more than doubled. They would have you to believe that just happens; it's an accident. We know better.

The same study found that one in five middle school students who reported using e-cigarettes have never even tried a conventional cigarette. This wasn't about finding a way off of smoking. This suggests, for many young people, was a gateway to nicotine addiction and to smoking.

The new study, by GAMMA, goes even further. Middle and high school students who use these cigarettes are more likely to smoke traditional cigarettes, less likely to quit smoking. This didn't come from some liberal think tank; JAMA Pediatrics. According to the 2014 Surgeon General's report, many kids and young adults who are occasional smokers go on to become daily smokers; 2,100 of them every single day.

I'm not going to give the whole statement here, but there is one part of it that I do want to refer to because it harkens me back to an era, Senator Markey, that you will remember well. It was 30 years ago, if you can recall this time, when those seven tobacco company executives appeared over in the House of Representatives and took an oath that cigarettes and tobacco were not addictive.

Now, Lorillard, one of the executives represented Lorillard, Lorillard is back arguing they don't market to kids. Look at the analysis recently published in the *Journal of Pediatrics*. Between 2011 and 2013, exposure to e-cigarette marketing by children age 12 to 17 rose 256 percent; 24 million kids saw these ads. That's no accident in the world of big business. Lorillard's blu e-cigarette accounted for 80 percent of this advertising targeted at 12 to 17 years old.

It's the same battle, Mr. Myers. We've been at it before. They want to addict these kids, this time to an e-cigarette which has a chemical that's addictive. We know what it leads to. Sadly, it leads to tobacco addiction, disease, and death.

I don't believe there is a case to be made for e-cigarettes being sold to children. I hope this committee feels the same way.

The CHAIRMAN. It does.

Thank you, Senator Durbin.

Senator Markey.

**STATEMENT OF HON. EDWARD MARKEY,  
U.S. SENATOR FROM MASSACHUSETTS**

Senator MARKEY. Thank you, Mr. Chairman.

And, just going back to Dick Durbin, that was a historic debate on the House floor. And that was the beginning of the banning of smoking on airplanes in the United States. And we still are in your debt, Dick, for that day. It changed the whole course of history.

My father died from lung cancer. He smoked two packs of Camels a day. He told me at age 12, he said he knew I'd be starting to smoke very soon. He said to me at age 12. So that's the year he started to smoke and he knew I would too. And he was urging me not to, as well as my mother, at age 12 because my father knew, then, that when he started smoking, maybe in 1930, that the same things was going to be true when I was a boy and the same thing is true today for boys and girls. That's when the temptation is greatest and that's when we have to be most aware of it, because the marketing to them is what makes it seductive and then, once you got them, you got them for life.

And so, that's really why we're having this hearing, because the marketing of this, the allure of this, is so superficially attractive that we know that all of history tells us; that it's targeted at young people, at kids. And it has always been that way. And I miss my father and I wish he had never smoked two packs of Camels a day, but he couldn't break the habit once he was into it. Once you're on, you're on.

So we know the technology is a very good thing. We have transformed rotary phones into iPhones; turned sunlight and wind into electricity; and plants into lifesaving drugs. There are certain things, however, that do not need to be reinvented, repurposed, or modernized; items that served no societal benefit whatsoever. The cigarette is one of them.

Yet, new cigarettes have exploded into the marketplace known as everything from e-cigs to advanced nicotine delivery systems to vaporizers. Like many other new technologies, these products are designed to appeal to youth, more accessible to youth, and are explicitly marketed to youth. And because of this, we are focused on a re-visitation of the history books. We know what happened in the past, we know what's happening right now.

After more than four decades of research there are several incontrovertible facts. Nicotine is addictive. It affects brain development. And, in combination with tobacco, it is responsible for claiming millions of lives. These facts are true and were true two decades ago at the same time as Big Tobacco willfully, consistently, publicly, and falsely denied them.

Today, e-cigarette sales in the United States, alone, top \$1 billion. Use of e-cigarettes by high school students doubled in just 1 year. And more than 20 percent of middle school kids, typically age 12 to 15, who use these cigarettes, have never smoked a traditional cigarette.

This data is not at all surprising when one considers the way these nicotine delivery products market particularly to youth and

now these products are available in a myriad of flavors from cotton candy to Kool-Aid grape.

In the 1950s, just appealed cigarettes claimed that they were the best for you and left a clean, fresh taste in the mouth and today white cloud e-cigarettes promises the gift of fresh air. In the 1940s, Phillip Morris promised their product will provide freedom from throat irritation, and Virginia Slims and other tobacco companies advertised cigarettes as touches of freedom that equated smoking with women's rights.

Today, blu cigarettes have a campaign called "Take Back Your Freedom" promoting the use of their products in spaces where traditional smoking is not allowed. End of the 1970s, Lorillard advertising executives suggested walking a fine line in packaging designed to ensure that packaging was geared to attract the youthful eye, not the watchful eye of the Federal Government.

Today's electronic cigarettes are no better than the Marlboros of the 1950s. Cotton Candy-flavored vape liquid can contain just as much nicotine and sometimes more as a traditional cigarette. Cherry Crush e-cigs pose the same addiction risk as Joe Camels of the 1970s. And we know from years of research that flavors attract young people. And the younger a person is when they start tobacco use, the more difficult it is to stop. We know that if a kid hasn't started to smoke by the age of 19, they're not going to start. We just know that's a rule.

So you got to get them before 19, because all the social pressure is no longer effective anymore. OK? Just a rule.

So you have to market younger. That's just the way it works. Get fine replacement customers for those who have died.

So, Dr. Tanski, if you could give me a yes or a no, is the nicotine that is present in e-cigarettes and e-liquids any less addictive than nicotine in traditional cigarettes?

Dr. TANSKI. It is no less addictive than anything in a traditional cigarette.

Senator MARKEY. Mr. Weiss, Mr. Healey, do you agree with Dr. Tanski that your products are just as addictive as traditional cigarettes?

Mr. HEALEY. I agree that it contains nicotine and we do acknowledge that nicotine is addictive.

Mr. WEISS. Yes.

Senator MARKEY. So you agree.

Do you agree with that, Mr. Healey?

Mr. HEALEY. Yes.

Senator MARKEY. And so, let's go back over to you, Mr. Myers. If that is the case and they're addictive, than what possible argument can they make in order to keep these products on the market or targeted toward children?

Mr. MYERS. It's particularly the reason we're concerned about the kind of marketing that we've seen in the use of flavors that we think have traditionally been shown to appeal to children.

Senator MARKEY. For many, the thought of Santa Claus brings back nostalgia of childhood cookies and big white beard. Most children would think of Santa needing e-cigarettes despite this social media promotion to the contrary. Other examples, including images

of cartoons like blu's Mr. Cool, bring back flashbacks of similar strategies used by traditional tobacco companies.

Mr. Myers, do you think there is a chance that these images could appeal particularly to young consumers?

Mr. MYERS. I think there's no question about that. And our concern is it's a generation of consumers who have been protected from this kind of advertising. And so, it's the first time they'll see them.

Senator MARKEY. Do you think it's a coincidence that it's actually called "cool" in the same way that Kool cigarettes with a "K" back in the earlier age was meant to be the entry level for a kid to finally reach Camels, but it would be a softer entry for the kid to be able to go Kool first and then move on to the harder cigarette?

Mr. MYERS. It requires a level of disbelief to believe that it could possibly be a coincidence.

Senator MARKEY. So "cool" was a word then and it's a word now, and each time it's just kind of trying to get the young kid into the pattern of smoking cigarettes.

Mr. Weiss, Mr. Healey, do you agree with Dr. Myers about that? That that's really what the intention is to entice a kid into doing something that's cool, that's ultimately going to potentially lead to real health consequences for that young person?

Mr. HEALEY. Absolutely not.

Our product is intended for adult smokers. I could understand the opinion if smoking wasn't and we created smoking. We didn't. We created our product for smokers to get them away from combusted cigarettes.

Senator MARKEY. Mr. Weiss, Mr. Healey, in your testimonial and materials presented to the Committee, you repeatedly state that your target audience are adults and we continue to hear it right now. Will your companies commit to not using these types of materials that could be to particularly appeal to children? Will you agree not to use that kind of advertising?

It was used when I was a boy, you're using them again today, we know why young kids used to say, "I think I'm going to smoke Kools first." So will you agree not to use that kind of advertising going forward in the future?

Mr. HEALEY. We've removed at least a year ago, so we commit to never using that again. Correct.

Senator MARKEY. Well, will you commit to not using any kind of cartoons in the future, Mr. Healey?

Mr. HEALEY. I will agree to that, yes.

Senator MARKEY. Will you agree to that, Mr. Weiss?

Mr. WEISS. Yes. Yes.

Senator MARKEY. No cartoons in the future.

Mr. WEISS. Correct.

Senator MARKEY. Will you commit to going through your social media sites to erase any past images such as those that appeal to those who are young kids?

Mr. WEISS. Yes. Absolutely, rigorously go through and we'll continue to do so.

Senator MARKEY. Will you agree with that, Mr. Healey?

Mr. HEALEY. I believe blu already has. Yes, Senator.

Senator MARKEY. Dr. Tanski, several e-cigarette company brands use advertising to create the impression that e-cigarettes are a way

to eliminate traditional cigarette use altogether. This has been acknowledged by the American Legacy Foundation, who in a recent report stated that some brands focus their message more responsibly on smokers to quit combustible use. Let's briefly view a recent television ad by FIN e-cigarettes, a brand that has recently surged in popularity.

[Video shown.]

Senator MARKEY. So, to repeat the closing line, "There was a time when no one was offended by it." Just smoking amongst other people indifferent to how it might impact on them. But "That time has come again" says the ad. The message seems to be promoting smoking as a new favorite pastime for young attractive consumers.

Dr. Tanski, based on your review of e-cigarette marketing messages, do you have any concerns that these products are glamorizing smoking in general?

Dr. TANSKI. Yes, I do, Senator Markey.

It's clear that many of these images are quite glamorous and quite attractive and they really are taking a lesson from the 1950s playbook of the tobacco companies. And that is of significant concern as we've all heard. And I just want to make a point that when kids, when young people, see these ads or see these ads or see people who are using electronic cigarettes or the vaping devices, it's very indistinguishable for a young person to make the distinction between what is someone who is smoking versus someone who is vaping.

My own kids were pretty savvy. They're 13 and 11 years old and they know what I do. And I've shown them pictures and videos of people who are vaping and I say, "What are they doing?" And they'll say, "They're smoking a cigarette."

So it's very difficult for kids, in particular, to understand that there's a difference. And so, we really are seeing, I fear, a re-normalization of that kind of image and behavior. And it's glamorous, it's sexy. They've got very cute models who are vaping and our kids don't recognize the difference. So it really is significant cause for concern.

Senator MARKEY. Do you agree that the blu's tagline "Nobody likes a quitter" may be encouraging continued nicotine and tobacco use by those who would otherwise quit altogether?

Dr. TANSKI. That, again, is a significant concern; that we're maintaining dual use rather than getting people quit their combusted tobacco products.

Senator MARKEY. And let me, just Mr. Healey, many corporate companies collect data about their customers to better serve and deliver products. Do you collect information about the demographics of you customers?

Mr. HEALEY. Yes, sir. We do.

Senator MARKEY. Could you provide the age demographics and other information about your current users of your products to the Committee?

Mr. HEALEY. Yes, I could.

Our average consumer is 51 years old, but we can give you the total data supplement the record.

Senator MARKEY. Mr. Weiss, would you do the same for the Committee?

Mr. WEISS. Yes.

Senator MARKEY. OK. I thank you so much.

I think that we know what's going on here. You don't have to be Dick Tracey to figure this out. And we understand the advertising, we understand who it is being marketed to, we understand that you got to get someone under 19 to start smoking or else you've lost the most likely as a customer.

So, Mr. Chairman, I thank you for this hearing. I am fortunate, I never had a cigarette in my life but that was just because my father knew he had made a big mistake. And he made it, along with my mother, very strong admonition to me. But this was just an avoidable catastrophe. And we just have to make sure that other young people, who were not protected the way I was, aren't actually made vulnerable by the marketing of these companies. Because, otherwise, it's just another gateway like Kools cigarettes used to be into the worse that can happen to some of my health perspective.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Markey.

We're going to have a second round because, if Senator Blumenthal doesn't ask for a second round, I'm not going to speak to him.

Senator BLUMENTHAL. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Nelson.

Senator BLUMENTHAL. I would respectfully request a second round.

The CHAIRMAN. Before you start, I'm going give my conclusion.

I think this whole thing is nothing more than it's all about the money. I think it's uncreative. I think it's nasty. It's like pornography; in my mind. What's to pick between the one and the other. In fact, maybe what you're doing is much more dangerous.

I'm ashamed of you. I don't know how you go to sleep at night. I don't know what gets you to work in the morning except the color green of dollars. I've never said anything like that before, but I've never, in my 30 years on this committee, have I ever heard testimony such as given by you, so too by—so and by you, sir.

What I want to do is send you to the Middle East because you say we can just get good people together and we can settle everything. You should go to the Middle East and settle that. Then, come back, and you can talk to us more realistically.

But, for you two, you're what is wrong with this country. And the profit motive is good, but only if it's aimed at something which is for the general benefit of the public. And that can be stretched a little bit because the public likes to be entertained. I can't say professional basketball is necessary for the existence of democracy in America but people like it so let's go ahead.

But I think, in your case, you don't have that leeway. It's simply a matter of the dollars, the money that you rake in; the 256 percent increase in 2 years in advertising. And then you say it's only for the adults; it's not for the children when everything else that's come out of this hearing says otherwise. I think it's dreadful.

I yield to Senator Blumenthal.

Senator BLUMENTHAL. Thank you, Mr. Chairman. And thank you for giving us a second round and, again, thank you for holding this hearing.

I want to begin by joining Senator Durbin in thanking Matt Myers for his long-standing historic and heroic efforts in this area, which goes back decades. And, in fact, we've worked together for a couple decades on nicotine addiction and tobacco use, which are a continuing problem in this country. Let us never forget, despite the fact that this hearing is on e-cigarettes, that the evil of tobacco and cigarette use remains as a primary cause of death and addiction in this country. And if there is a redeeming fact about your products, it is the possibility that it offers quick mechanisms, yet unproven, but at least perhaps a glimmer of hope.

It's the advertising and promotions and the pitches that bring us here today. So let me begin this second round of questioning on a, sort of, positive note: in the war against Big Tobacco, so-called, I was privileged to lead that effort close to 20 years ago with lawsuits that eventually led to settlements that produced great advances. Not alone, because it took an act of Congress in the Tobacco Control Act to take another step. And we still have more steps to go in the battle to redeem public health in that area.

But let me ask you, would you be willing to come together, to sit down, to commit to reaching a settlement and agreement; a protocol that stops any possible ads and pitches that appeal to children and teenagers?

Mr. WEISS. I'll answer for NJOY.

We are committed to not—we do not want to attract anyone who is not an adult smoker to our products and we have committed to FDA regulation; we've been long supporters of FDA regulation for the category; for them to make the science-based data driven decisions.

Senator BLUMENTHAL. I'm asking you to commit to something more specific, which is to join in talks, specific discussions, involving others in the industry, the major players, just as happened in the tobacco area that would produce protocols and agreements. For example, to avoid use of TV; to avoid of cartoon characters; to require identification at point of sale; similar to what was done in the tobacco area.

Mr. WEISS. We would be willing to have the conversations. I wouldn't be willing to restrict television advertising because it's an effective means of advertising—

Senator BLUMENTHAL. Well, of course it is, it's an attractive means to reach children.

I'm asking you to join in conversations that would involve others in your industry. And I'm asking this question of Mr. Healey as well. It would at least consider what has been true of the tobacco industry; it's avoidance of the use of TV ads.

Mr. HEALEY. I would welcome the ability to sit down and discuss it. As I said earlier, it's not my intention to sell this product to children. It's the 41 million smokers. So I am not averse to sitting down and discussing all possibilities of how we do that and eliminate tobacco.

Senator BLUMENTHAL. And we're not talking here about intent, because I am sure that your companies have not done what the to-

bacco industry did, which is to do marketing studies that we've discovered when we brought lawsuits that showed that despite all their claims under oath, in fact, they had studies showing that their marketing tactics were aimed at children, had the effect of reaching children and appealing to children. I know you're a lot smarter. You don't have those studies in your files.

But in this hearing is not about you say what your intentions are, it's about what the effects are of your marketing strategies, your promotions, your use of celebrities. And let me just show you just to complete some of the tableau here. I am sure, Mr. Healey, you recognize this individual.

[The picture referred to follows:]



Mr. HEALEY. That's Jenny McCarthy.

Senator BLUMENTHAL. And you know what product she's using.

Mr. HEALEY. blu.

Senator BLUMENTHAL. And would you deny that this kind of promotion appeals to teenagers and children?

Mr. HEALEY. I would deny that.

Senator BLUMENTHAL. You would?

And even though she's a celebrity, even though she's in an obviously suggestive pose here, you would deny that it has any appeal to teenagers and children.

Mr. HEALEY. Yes. I would deny that.

Senator BLUMENTHAL. Would you say she is smoking in this promotion?

Mr. HEALEY. She's vaping.

Senator BLUMENTHAL. Vaping.

So to go to the point that was made earlier, you don't see any confusion between smoking and vaping in this ad or any of your other promotions?

Mr. HEALEY. Of course there is some confusion but, in order to defeat tobacco and cigarettes, we have to appeal to smokers.

Senator BLUMENTHAL. Let me show you another official document from your company. It's on your website, is it not, as part of

what you have called the Lorillard Inc. Smoking Prevention program? Do you recognize it?

Mr. HEALEY. No, I don't. I'm here to represent blu, not Lorillard. So I'm not sure where that's from?

Senator BLUMENTHAL. It's your parent company; isn't it?

Mr. HEALEY. I don't even know what it is you're showing, sir.

Senator BLUMENTHAL. Well, let me—can I have one of the staff give it to—and by the way, Mr. Chairman, could I have all of these documents and the visuals shown by both Senator Markey and myself and others on the Committee made part of the official record?

Thank you.

Do you recognize that document?

Mr. HEALEY. I believe it's from—I forget the technical name but the site that Lorillard sponsors but they're not responsible for the messaging or have any editorial control. But, again, I'm here to speak for blu, this is not—

Senator BLUMENTHAL. Well, if it's a Lorillard document or if it's on Lorillard's website, you're saying Lorillard's not responsible for it?

Mr. HEALEY. This is not on Lorillard's website.

Senator BLUMENTHAL. Is it on yours?

Mr. HEALEY. No. It's not on mine either.

Senator BLUMENTHAL. So it is not part of "Real Parents Real Answers: What you need to know about e-cigarettes Infographic?"

Mr. HEALEY. I assume it is, but—

Senator BLUMENTHAL. You assume it is? You've never seen it before?

Mr. HEALEY.—I've never looked at the site in-depth.

Senator BLUMENTHAL. You've never looked at the site in-depth even though you are here representing blu; are you not?

Mr. HEALEY. Correct.

Senator BLUMENTHAL. Well, let me just ask you then, as someone who has never seen it before. It says "For the first time in 43 years, 'smoking' ads are returning to TV with advertising." And you'll have to accept my representation that this is part of a presentation called "Real Parents Real Answers." It's sponsored by Lorillard Inc.'s Youth Smoking Prevention program. And it says that smoking ads are returning to TV.

Are those your ads?

[The information referred to follows:]



Mr. HEALEY. Well, our ads would be some of them, yes.

Senator BLUMENTHAL. And it says “Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, piña colada and berry.” That’s a warning about flavors; is it not?

Mr. HEALEY. That’s an opinion of the person that created the site.

Senator BLUMENTHAL. The person who created it and it might be Lorillard. But, of course, you haven’t seen it before.

Mr. HEALEY. Lorillard did not create this site and all of it in the business behind it, they sponsored it. And at the bottom of the site it even states that the site is the opinion of the doctor; not Lorillard.

Senator BLUMENTHAL. Well, let me show a couple of charts on flavors.

Would you say that this kind of promotion or ad appeals to children?

Mr. HEALEY. It’s completely inappropriate and I would agree with you.

Senator BLUMENTHAL. And it’s a part of what the industry does. Yes or no?

Mr. HEALEY. Its one brand in particular, I believe. It’s not what I do or my—

Senator BLUMENTHAL. So wouldn’t you agree that as a “responsible” marketer, and you’re in the business of promoting and selling these products, that an industry-wide agreement to ban those kinds of cartoon characters would be a good thing?

Mr. HEALEY. Banning cartoon characters in the use of our advertising, I agree.

Senator BLUMENTHAL. So would you commit to come together and reach another master settlement agreement that provides for a ban on this type of inappropriate marketing, the use of people like Jenny McCarthy, sports and rock concert sponsorships, all of these kinds of same protocols in agreement with the result of the tobacco industry coming to the table? Would you agree to do it?

Mr. HEALEY. I would agree to sit down to discuss how we effectively eliminate tobacco, but I would not sit down to discuss how I relinquish my first amendment rights and losing focus of the big picture; that we could eliminate tobacco here.

Senator BLUMENTHAL. Well, may I suggest, respectfully, that I would have more respect for all of the answers that you’ve given today knowing that you’re the messenger but you don’t make the policy if your companies would commit to help lead and make yourselves part of the solution, not the problem. And the problem here, I just want to stress again, I’ve said it repeatedly, is not your product. I’m not passing judgment on your product. There’s not enough science to draw conclusions, as yet. I view it skeptically as a means of quitting or cessation. But, I’m not passing judgment on the product. I’m passing judgment on the marketing and promotion which create a clear and present danger of addicting another generation.

Addicting another generation to nicotine, which is among the most powerfully addictive drugs known to man, and it is, in fact, the ingredient in cigarettes that makes them so pernicious and insidious because it hooks the user to a device that kills them. Ciga-

rettes kill people. And if your products are a gateway to cigarette use, they are aiding and abetting at killing.

So I hope you'll rethink some of your answers. I hope that we will have another forum where we can revisit some of these issues and that we can move constructively toward some kind of solution.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Blumenthal.

Senator Nelson, I think you had a question.

Senator NELSON. Earlier in my comments, I noted to the toxicity of the concentrated nicotine in an e-cigarette refill liquid. Let me ask the two gentlemen, Mr. Healey and Mr. Weiss. In addition to the nicotine, what are the other ingredients in the liquid nicotine?

Mr. HEALEY. Speaking to the blu product, the five key ingredients are propylene glycol, glycerin and vegetable glycerin, distilled water, nicotine and natural and artificial flavors.

Mr. WEISS. And in our product it's nicotine, propylene glycol, glycerin and also flavorings.

Senator NELSON. Are any of those, other than the nicotine, harmful substances?

Mr. WEISS. We've tested our products and we support the FDA's HPHC, Harmful and Potentially Harmful Constituent, testing for these products. And we've submitted our results to the FDA and are very comfortable with the results that they are, orders of magnitude, safer than combusted cigarettes.

Senator NELSON. But, as to the substance itself being harmful or not, I didn't understand your answer.

Mr. WEISS. So the substances are generally regarded as safe in foods. They haven't been tested in terms of academia logical studies and inhalation in humans over large periods of time.

Senator NELSON. Do you make a complete listing of all these substances in the e-cigarette liquid available to the public?

Mr. WEISS. Yes, I do. It's on our website.

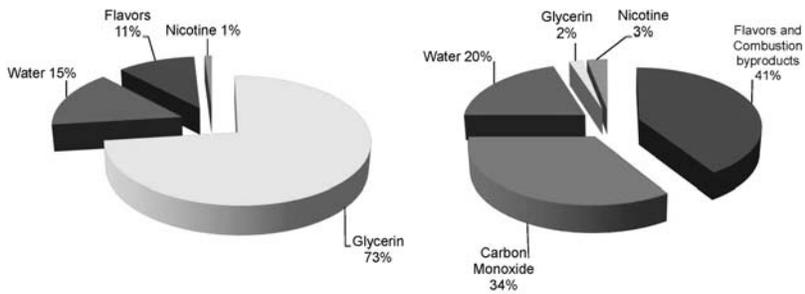
Mr. HEALEY. Yes, sir.

Senator NELSON. I would just note for the record and ask that it be inserted.

[The information referred to follows:]

## blu e-cig aerosol is mostly glycerin and water

Analysis based on internal research conducted for blu with intention to be published in a peer reviewed publication in 2014.



**blu e-cigarette aerosol  
99 Puffs**

**Market Leading Gold cigarette  
9 Puffs**

## Harmful constituent yields for blu e-cigs are similar to air... and far lower than cigarettes

| Constituent Class | Market Leading Gold Cigarette 9 puffs (1 cigarette) | blu Product 99 puffs | "Air" 99 puffs | blu Product minus "Air" 99 puffs | % less in blu vs. cigarette |
|-------------------|---|----------------------|----------------|----------------------------------|-----------------------------|
| Carbon Monoxide   | 27 mg   | < 0.1 mg             | < 0.1 mg       | Not measurable                   | 100%                        |
| Carbonyls         | 1.86  | < 0.06               | < 0.05         | 0.01                             | 99.5%                       |
| Phenolics         | 0.204   | < 0.001              | < 0.001        | Not measurable                   | 100%                        |
| Volatiles         | 1.430   | < 0.001              | < 0.0004       | 0.0006                           | 99.9%                       |
| Metals            | < 0.00020   | < 0.00004            | < 0.00004      | Not measurable                   | 100%                        |
| TSNAs             | 0.000550  | < 0.00002            | < 0.00002      | Not measurable                   | 100%                        |
| PAA               | 0.000024  | < 0.000004           | < 0.000004     | Not measurable                   | 100%                        |
| PAH               | 0.00222   | < 0.00016            | < 0.00015      | 0.00001                          | 99.5%                       |

Analysis based on internal research conducted for blu using the Canadian Intense Smoking Method; intend to publish in a peer reviewed publication in 2014

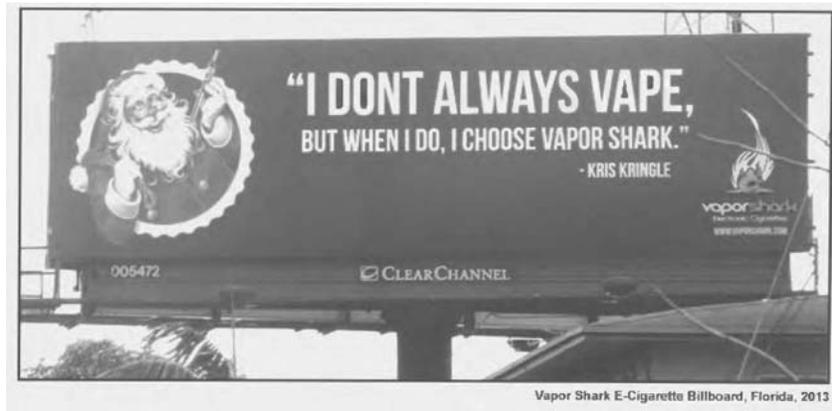
Senator NELSON. It has just been brought to my attention. Here's a billboard at Christmas time in Miami, on I-95, a picture of what appears to be a Santa Claus-like figure. "I don't always vape, but when I do, I choose a Vapor Shark—Kris Kringle."

So you are utilizing the seasons of the year.

I would add this to the record, Mr. Chairman.

The CHAIRMAN. It will all be included.

[The picture referred to follows:]



Senator NELSON. Models, very attractive models, all promoting these products.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you all and the hearing is adjourned.

[Whereupon, at 4:49 p.m., the hearing was adjourned.]



## A P P E N D I X

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. DEAN HELLER TO  
DR. SUSANNE E. TANSKI

*Question 1.* Regarding a national standard on age

(a) Should a national standard prohibiting sale of electronic cigarettes to any person under the age of 18 years old exist?

Answer. The American Academy of Pediatrics (AAP) is dedicated to eliminating all tobacco use among children and youth, and as such, strongly supports national standards prohibiting the sale of all tobacco and nicotine delivery products, including all electronic cigarettes, to those under 18 at a minimum, or to a higher age standard designed to protect youth from addiction.

(b) Should the Food and Drug Administration or the Federal Trade Commission enforce this standard and why?

Answer. The Tobacco Control Act gives the Food and Drug Administration the resources and authority to help enforce purchase age restrictions for cigarettes and other tobacco products that the FDA currently regulates. We believe that the FDA should expand the national minimum purchase age restriction to electronic cigarettes and is the appropriate agency to enforce such a restriction.

(c) Should the measure be limited to only an electronic device that employs a battery to power a heating chamber that converts a liquid solution containing nicotine or are there other vaporizing devices that do not fit the description mentioned that should also be prohibited for sale to minors?

Answer. No vaporizing device—whether designed for vaporizing liquid nicotine, non-nicotine solution or whole tobacco/herb—has been proven to be safe in the pediatric population. Even absent nicotine, there are potential negative health consequences associated with inhaling the vapor of electronic cigarettes into the still-developing lungs of a child. In addition, there is a serious risk that if non-nicotine containing vaporizing devices were allowed to be sold to children, that they would serve as starter products for youth that may eventually lead them to try nicotine-containing products or even traditional cigarettes. Therefore, the AAP would support purchase age restrictions for all vaporizing products, including those designed for liquid and whole leaf vaporization.

*Question 2.* Regarding flavors

(a) How should policy account for the phenomenon of flavor appearing to be a positive reason for adult smokers to want to switch from combustion to e-cigarette products that offer novel flavor alternatives?

Answer. FDA-approved nicotine replacement therapies (NRT) do come in limited flavors other than tobacco for individuals attempting to quit smoking who may prefer not to use tobacco-flavored products. Unlike e-cigarettes, NRT have been approved by the FDA on the basis of clinical evidence demonstrating safety and efficacy in aiding smoking cessation and is marketed to existing adult smokers for the purpose of smoking cessation. Largely because of the limited way in which NRT products are marketed as well as the way that NRT are absorbed, there is low abuse/addiction potential of these products and experience has shown that youth do not use NRT for non-therapeutic use. Unfortunately, in contrast we have seen dramatic increases in the number of youth using e-cigarettes. We believe this increase is directly linked to marketing and candy and other attractive flavorings that appeal to children and youth. We do not yet have data to understand how the nicotine from various vaporizing devices is absorbed, so the addiction potential of these devices with or without flavoring is unknown. In the absence of this data regarding addiction potential, the AAP believes that the use of candy and other flavors in e-cigarettes should be prohibited as it is well known that flavored tobacco products are attractive to youth.

(b) What is the risk that a ban on flavors would make switching away from combustion cigarettes relatively less appealing?

Answer. We do not know what this risk is, if any, and we understand the difficulty with balancing any potential benefit of electronic cigarettes to the public health in the absence of data. First and foremost, however, we believe we need to ensure that we do not addict a new generation of Americans to tobacco. As such, we must regulate e-cigarettes in a way that limits adolescent use of these products to the lowest possible level. The use of candy and other flavors in e-cigarettes is particularly concerning when coupled with advertising and other marketing practices that are attractive to children. In spite of claims to the contrary, these advertisements appeal to an audience broader than current adult smokers. Any e-cigarette or other nicotine vaporizing product could theoretically seek FDA approval as a smoking cessation device. It would be conceivable that FDA could determine that the use of flavors would be appropriate in cessation, so long as there were appropriate safeguards to prevent adolescent use.

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RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. DEAN HELLER TO  
MATTHEW L. MYERS

*Question 1.* Regarding a national standard on age

(a) Should a national standard prohibiting sale of electronic cigarettes to any person under the age of 18 years old exist?

Answer. I support the provision in the Family Smoking Prevention and Tobacco Control Act that established a national minimum age of 18 for sale for cigarettes and smokeless tobacco products and the accompanying requirement for verification of age, and I support applying those requirements to e-cigarettes and other tobacco products not currently regulated by the FDA. Regardless of how one weighs the potential benefits and risks of e-cigarettes, all should be able to agree that youth should not be using them. The fact that e-cigarettes typically deliver nicotine, a highly addictive substance that also impacts adolescent brain development, is reason enough for the Federal Government to take steps to reduce youth use of e-cigarettes, including the establishment of a minimum age of 18 for sale of this product. It is also important to note that states should remain free to impose a higher minimum age of sale if they consider it appropriate.

I would also note that it is important that the regulation of products that deliver nicotine needs to extend beyond a minimum age of sale and should cover each of the subject matter areas included in the Family Smoking Prevention and Tobacco Control Act.

(b) Should the Food and Drug Administration or the Federal Trade Commission enforce this standard and why?

Answer. The FDA should enforce a national minimum age of sale for e-cigarettes. The FDA already has been given the legal authority necessary to enforce the minimum age of sale requirement and has established a mechanism for coordinating with the states, educating retailers and enforcing the national minimum age of sale for cigarettes and smokeless tobacco products that could be easily extended to e-cigarettes. The FDA has tools and an existing legal structure as well as an ability to enforce a national minimum age of sale that the FTC does not possess. In addition, the FDA possesses the legal and technical capacity to regulate e-cigarettes more comprehensively, and it is essential that there be a comprehensive approach to the regulation of e-cigarettes.

(c) Should the measure be limited to only an electronic device that employs a battery to power a heating chamber that converts a liquid solution containing nicotine or are there other vaporizing devices that do not fit the description mentioned that should also be prohibited for sale to minors?

Answer. Given the wide variety of e-cigarettes on the market and the rapid changes that are occurring in the e-cigarette market, the broadest possible definition should be applied so that all products that deliver nicotine should be regulated by the FDA, either as a tobacco product or as a drug delivery device. Sales of products that deliver nicotine should not be permitted to people under the age of 18 unless it is an FDA-approved tobacco cessation product prescribed by a health professional.

*Question 2.* Regarding flavors

(a) How should policy account for the phenomenon of flavor appearing to be a positive reason for adult smokers to want to switch from combustion to e-cigarette products that offer novel flavor alternatives?

Answer. There is inadequate scientific evidence to conclude that flavors in general or that specific flavors are either essential or significantly increase the effectiveness of e-cigarettes in helping cigarette smokers quit. If any manufacturer believes that

the addition of specific flavors can be shown to increase the effectiveness of e-cigarettes in helping cigarette smokers quit smoking cigarettes, the evidence should be presented to the FDA for objective, independent review and analysis. To date, e-cigarette manufacturers have sought to avoid the type of meaningful regulation that applies to products regulated by FDA, putting the public at risk—both in terms of potential harm to adults and increased risk of youth tobacco use.

There have been no studies presented that meet the normal standards set by the FDA for evaluating the impact, efficacy or potential harm of adding ingredients, such as flavors. This is especially important in this situation for multiple reasons: (a) There are flavoring agents that are not harmful when consumed in one form that become carcinogenic when burned or heated and inhaled. There is no evidence that the flavors being used by the e-cigarette companies across the board have been evaluated for this purpose; (b) There is substantial reason for concern that some, if not many flavors, may increase youth use of nicotine. Given the rapidity of the introduction of different flavors by many manufacturers, it is clear that no testing is being done to minimize the risk that the flavors being introduced will increase youth tobacco use.

Nicotine doesn't cause cancer, but it is not benign. Ingredients that may expand the appeal of nicotine-based products to non-tobacco users or former cigarette smokers should be first subjected to the type of independent scientific review that FDA applies to other products. Manufacturer claims based on studies that fall far below the standards traditionally established by FDA are not an adequate substitute. The reality is that not a single rigorous study has been presented to the FDA or any other Federal agency that would support a claim or the conclusion that the addition of the type of flavors that the e-cigarette industry is using meets any reasonable standard of efficacy in helping cigarette smokers end their use of cigarettes.

On the other hand, there is reason to be concerned that the addition of fruit and candy flavorings to e-cigarettes will broaden the appeal of this product to non-smokers, including kids, who would find the flavor of tobacco distasteful. Today, e-cigarette liquids come in an ever growing variety of flavors, including vivid vanilla, cinabon, cherry crush, chocolate, jolly rancher, gummi bear, bubble gum, and cotton candy. Congress explicitly banned the sale of cigarettes with similar characterizing flavors because of their appeal to youth. In cigars, where use of flavors is still permitted, researchers have found that youth and young adults prefer cigar brands that come in a variety of flavors, and that preference declines significantly with age.

The two Internet surveys that have been referenced by the e-cigarette industry are by no means adequate to conclude either that flavors are effective in helping cigarette smokers quit or that they don't appeal to youth.

The evidence is strong enough that flavored tobacco products appeal to kids and may increase the number of kids who will use them for FDA to prohibit their use in e-cigarettes, unless and until adequate scientific evidence is presented based on adequate testing that the use of specific flavors does increase the ability of cigarette smokers to switch entirely away from cigarettes and that these flavors can be added and marketed without appealing unduly to youth or other non-cigarette smokers.

The proper approach is for FDA to evaluate the science and decide whether the use of flavors in e-cigarettes is appropriate or should be prohibited. Congress gave FDA the authority to make determinations like this so that a science-based process is used to determine what is appropriate for the protection of public health.

(b) What is the risk that a ban on flavors would make switching away from combustion cigarettes relatively less appealing?

Answer. The proper way to evaluate both the risk of using flavors and their benefit is to require e-cigarette manufacturers to submit their scientific evidence to FDA. For sound reasons, Congress has given the FDA the authority to evaluate the relative health impact and risk of tobacco products. It is the best way to protect the American public. If there is sound scientific evidence that certain flavors will help cigarette smokers quit, it should be submitted to FDA. FDA was created so that the American public would not become human guinea pigs for every manufacturer of a potentially harmful product, and those protections should be extended to users of e-cigarettes.

The most serious risk to the public will come if the FDA regulatory process is circumvented. Companies that make NRTs are not allowed to add flavors without FDA review. No reason exists to allow e-cigarette manufacturers to do so.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. DEAN HELLER TO  
JASON HEALY

*Question 1.* Regarding a national standard on age

(a) Should a national standard prohibiting sale of electronic cigarettes to any person under the age of 18 years old exist?

Answer. Yes

(b) Should the Food and Drug Administration or the Federal Trade Commission enforce this standard and why?

Answer. The Federal Drug Administration (FDA) should enforce this standard because FDA has expressed its intent to regulate electronic cigarettes as tobacco products and age limits for the purchase and sale of tobacco products are established in the Family Smoking Prevention and Tobacco Control Act (TCA). More specifically, pursuant to Section 102 of the TCA, FDA issued final rules on March 19, 2010 that prohibits the sale of cigarettes and smokeless tobacco to persons under 18 years of age.

(c) Should the measure be limited to only an electronic device that employs a battery to power a heating chamber that converts a liquid solution containing nicotine or are there other vaporizing devices that do not fit the description mentioned that should also be prohibited for sale to minors?

Answer. The rule to prohibit the sale to persons under 18 years of age should apply to all products that contain nicotine, whether the products are traditional tobacco products, e-cigs, vapor products, nicotine liquid for vapor products, nicotine replacement therapies (*e.g.*, nicotine gums and patches), or any other products that contain nicotine.

*Question 2.* Regarding flavors

(a) How should policy account for the phenomenon of flavor appearing to be a positive reason for adult smokers to want to switch from combustion to e-cigarette products that offer novel flavor alternatives?

Answer. Policy should permit the responsible marketing of flavors that appeal to adults. It is commonplace for products marketed to adults to be offered in a variety of flavors. Beer and alcohol are available in numerous types of flavors enjoyed by adults, as are many types of coffee and tea. Most significantly, nicotine therapy products are also sold in a variety of flavors. For example, flavors of Nicorette gums and lozenges include White Ice Mint, Fruit Chill, Cinnamon Surge and Cherry.

While Congress banned cigarettes with a characterizing flavor other than tobacco or menthol through the TCA, it did not ban characterizing flavors for other tobacco products such as snuff or chewing tobacco. Responsible marketing and advertising practices, including the marketing of flavors that appeal to adults, can ensure that all adults who prefer flavors may continue enjoying them.

(b) What is the risk that a ban on flavors would make switching away from combustion cigarettes relatively less appealing?

Answer. If smokers do not like the taste of e-cigs, they are not likely to try or continue to use e-cigs. blu believes that using a variety of flavors is critical to keeping adult smokers who have switched to e-cigs from returning to more harmful combustible cigarettes. Research supports the importance of flavors in switching smokers. For example, a study published by Farsolino *et al.*, (2013) concluded that “[flavors] play a major role in the overall experience of dedicated users and support the hypothesis that they are important contributors in reducing or eliminating smoking consumption.” The study also found that tobacco is the preferred flavor when starting to use e-cigs but users later switch to other flavors, noting that a significant population of e-cigs users would be dissatisfied and/or less likely to quit smoking if flavored options were limited. blu’s experience with its consumers also supports that flavors are critical to switch adult smokers to e-cigs. blu’s online cartridge sales show approximately 50 percent of all sales consist of non-traditional flavors and that the average purchaser is 45 years of age.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. DEAN HELLER TO  
CRAIG WEISS

*Question 1.* Regarding a national standard on age

(a) Should a national standard prohibiting sale of electronic cigarettes to any person under the age of 18 years old exist?

Answer. NJOY strongly supports the provisions in FDA’s draft deeming rule establishing a national prohibition on the sale of electronic cigarettes (e-cigarettes), also known as electronic nicotine delivery systems (ENDS), to any person under the

age of 18 years old as well as requiring age verification based on photographic identification containing the bearer's date of birth (for all persons age 26 and younger). Additionally, as a company we impose contractual age verification obligations on retailers to prevent sales to minors. NJOY was among the earliest companies to support state bans on sales to minors and the first independent e-cigarette company to join the "We Card" program to prevent underage consumers from accessing our products. NJOY's position has been and remains that no minor should be using a nicotine-containing product of any kind. Please note the following provision related to minors in the warning label on our products: "NJOY products are intended for use by adults of legal smoking age (18 or older in California), and not by children, women who are pregnant or breastfeeding, or persons with or at risk of heart disease, high blood pressure, diabetes or taking medicine for depression or asthma."

(b) Should the Food and Drug Administration or the Federal Trade Commission enforce this standard and why?

Answer. NJOY believes that all regulations pertaining to ENDS should fall under the jurisdiction of FDA's Center for Tobacco Products (CTP). CTP's science-based approach and extensive body of specialized knowledge regarding the continuum of nicotine-containing products make CTP best suited to regulate this new product category and to do so in a way that properly considers the tremendous potential that these products are showing to reduce smoking-related harm. NJOY does not support Federal agencies other than CTP, such as the Federal Trade Commission (FTC) or Consumer Product Safety Commission (CPSC), neither of which contains the subject matter expertise or scientific resources of CTP, exercising new grants of authority regarding ENDS products. Rather, new areas of regulatory concern should come under the jurisdiction of CTP, which currently enforces the existing prohibition on sales of combustion cigarettes and smokeless tobacco to any person under the age of 18 in accordance with the *Family Smoking Prevention and Tobacco Control Act of 2009*.

(c) Should the measure be limited to only an electronic device that employs a battery to power a heating chamber that converts a liquid solution containing nicotine or are there other vaporizing devices that do not fit the description mentioned that should also be prohibited for sale to minors?

Answer. We strongly support CTP enforcing the aforementioned age restriction on sales of all known ENDS products (including disposable, rechargeable, and vaping products) and any other vaporizing devices capable of being used to deliver nicotine.

#### *Question 2. Regarding flavors*

(a) How should policy account for the phenomenon of flavor appearing to be a positive reason for adult smokers to want to switch from combustion to e-cigarette products that offer novel flavor alternatives?

Answer. The issue of flavors in ENDS has attracted a great deal of attention, with many expressing concern about the potential for certain flavors to entice youth into trying ENDS.

First, we note that considerable experience in the marketplace suggests that characterizing flavors are essential to displacing combustion cigarettes among current adult smokers. Large numbers of committed ENDS users no longer wish to use products with tobacco or menthol characterizing flavors once they have stopped smoking combustion cigarettes, "reset" their taste buds, and want fewer reminders of their prior combustion cigarette experience. Initial and growing evidence indicates that in such scenarios, ENDS users switch to products with characterizing flavors, including fruit, coffee, dessert, and beverage flavors. Moreover, data indicates that the use of flavors provides greater satisfaction, higher incidence of full conversion away from combustion, and lower incidence of dual use with combustion. Therefore, we believe that flavors with appeal to current adult smokers should be allowed by FDA as a mechanism for accelerating the displacement of combustion cigarettes—and that CTP should ensure that any policies on flavor are solidly based on science and do not slow the progression away from combustion smoking, or drive former smokers back to smoking.

Second, with respect to the concern over youth appeal, this concern does not appear to be well-founded. In this regard, NJOY conducted research to avoid selecting flavor descriptors that might appeal to non-smoking youth. To make this determination, the company commissioned a study of flavor appeal among non-smoking teens and adult smokers by respected tobacco control researcher Dr. Saul Shiffman of Pinney Associates and the University of Pittsburgh. The study results are currently being finalized for peer-reviewed publication shortly. In summary, the results show: the interest of non-smoking teens in e-cigarettes to be low; flavors do not increase non-smoking teens' interest; and flavors do increase adult smokers' interest in e-cigarettes, particularly those with certain characterizing flavors.

(b) What is the risk that a ban on flavors would make switching away from combustion cigarettes relatively less appealing?

Answer. NJOY's mission is to obsolete combustion cigarettes and the company offers only ENDS products. As noted above, NJOY's experience and research show that adult smokers are interested in flavors as part of switching to ENDS from combustion tobacco products.

An outright ban on flavors would make switching away from combustion cigarettes relatively less appealing, could drive former smokers back to smoking and/or perpetuate dual use of ENDS and combustion cigarettes—and therefore only entrench the smoking epidemic that costs 480,000 American lives annually.

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RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. JOHN THUNE TO  
SCOTT D. BALLIN

*Question 1.* Mr. Ballin, as we consider possible regulation of e-cigarettes, how do we ensure that the smaller players in this market can compete with the larger, more established tobacco companies, so as to encourage innovation that might lead to continued improvement and safety of the products?

Answer. First and foremost, there needs to be regulatory oversight of this rapidly growing industry. Second, protection of the public health must be given the highest of priorities but without stifling innovation and competition within the market place. Smaller companies that are true innovators, accept the importance of regulation, and have public health considerations as part of their business plans need to be given additional incentives and possibly allowed a longer period for adjusting to the market place regulations. This is something that is not unique to tobacco and nicotine products and has been applied by the FDA in areas such as food. The Center for Tobacco Products already recognizes the distinctions between small and large tobacco product manufacturers and the Tobacco Products Scientific Advisory Committee (TPSAC) has non-voting slots for both large and small manufacturers. While these slots reflect more traditional products and manufacturers it might be possible to add slots for novel alternative products—both large and small. That said, merely because a company is a smaller player should not be a justification for the development or marketing of an inferior product. It will be critical that as FDA moves forward with its deeming regulations and sets product standards that all players have ample opportunity to participate in the process.

*Question 2.* Mr. Ballin, in your testimony, you mentioned your work with the Institute for Environmental Negotiation at the University of Virginia on holding a series of safe haven dialogues to discuss tobacco and nicotine issues. At the hearing, Senator Blumenthal spoke about his work on the Big Tobacco lawsuits and settlement and asked Mr. Healy (blu eCigs) and Mr. Weiss (NJOY) about their willingness to “come together to sit down, to commit to reaching a settlement, an agreement, a protocol that stops any possible ads and pictures that appeal to children and teenagers.” While I think it may be a bit early to produce another master settlement agreement like that which was entered into between the four tobacco companies and the state attorneys general in 1998, do you have any further thoughts on how the industry and other stakeholders can get together to develop voluntary best practices for the industry?

Answer. My experience over the years, both as an active participant in dialogues (as part of the American Heart Association, the Coalition on Smoking OR Health, and the Campaign for Tobacco Free Kids), and now in working with the University of Virginia, is that “safe-haven” engagement with stakeholders and other experts does work. I appreciate Senator Blumenthal's raising the issue of “sitting down” but I don't think it should be for the purposes of “negotiating a settlement”. The e-cigarette industry is not “Big Tobacco” and is very diverse and as I said, the tobacco and nicotine environment is one that is rapidly changing with many challenges but more importantly many *opportunities*. Also critical is that unlike the days of the Master Settlement Agreement (MSA) we now have a fully funded regulatory agency in place where the bulk of the work can be done. As one who was actively involved in the “wars” with and against “Big Tobacco”, I think we need to realize that, as I and others have said, including FDA/CTP Director Zeller, we are in a “New Era”. We have a very unique opportunity to shape policy that both protects children and youth from the aggressive advertising and marketing of all tobacco and nicotine products (as well as access and use) and at the same time allows the 40 million smokers in this country the opportunity to switch to science-based lower risk products such as e-cigarettes. As to how we can move forward, there are a number of avenues to take. One is for the Food and Drug Administration to play a more active leadership role in convening workshops and generally engaging with a broad spec-

trum of stakeholders and interests in a transparent manner. Two is for interested stakeholders and interested parties to take an active role in the rule making process. Three is for there to be more private sector discussions in forums like those at the University of Virginia as well as in other venues, such as at the Food and Drug Law Institute, scientific conferences and other tobacco and nicotine conferences. Out of such meetings, forums etc there could possibly come a set of guiding principles developed specifically aimed at the e-cigarette industry that could be used as a tool to govern industry behaviors and practices as we await FDA regulations. During the hearing Chairman Rockefeller seemed to take the view that “sitting down” and actively engaging in discussions in a “safe-haven” venue was an act of futility. My own experiences and what I have seen accomplished at the FDA and in other forums respectfully, suggests otherwise.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. DEAN HELLER TO  
SCOTT D. BALLIN

*Question 1.* Regarding a national standard on age

(a) Should a national standard prohibiting sale of electronic cigarettes to any person under the age of 18 years old exist?

Answer. Yes. We need a national law that governs *all* tobacco and nicotine products, from the combustible toxic cigarette to the nicotine replacement products such as gums, patches and inhalers. This would also include all non-combustible products such as smokeless tobacco products, tobacco lozenges and e-cigarettes.

(b) Should the Food and Drug Administration or the Federal Trade Commission enforce this standard and why?

Answer. With respect to a national age requirement, the primary authority should clearly lie with the Food and Drug Administration. A comprehensive statute (Family Smoking Prevention and Tobacco Control Act) was enacted with that in mind and the agency has indicated that it is stepping up its enforcement activities in all of the states. The FTC authorities should be limited to what the agency already has which includes working and collaborating with the FDA when necessary and appropriate.

(c) Should the measure be limited to only an electronic device that employs a battery to power a heating chamber that converts a liquid solution containing nicotine or are there other vaporizing devices that do not fit the description mentioned that should also be prohibited for sale to minors?

Answer. No. As I indicated in my answer above, I believe that *all tobacco and nicotine products* should be regulated and that such products should not be allowed to be sold to anyone under the age of 18. I would go further to suggest that we need to have a serious discussion about whether authorities should extend to both *possession and usage* (as is done with alcohol and other products) by those under the age of 18. It seems that there is almost unanimous agreement that no minor should use tobacco, so it may be time to close this major loophole. Whether this might be done at the national level, at the state and local level or a combination of national, state, and local efforts remains to be determined. Perhaps, the FDA could ask the Institute of Medicine to look into the issue as they did with respect to alcohol.

*Question 2.* Regarding flavors

(a) How should policy account for the phenomenon of flavor appearing to be a positive reason for adult smokers to want to switch from combustion to e-cigarette products that offer novel flavor alternatives?

Answer. In discussing and setting policies for flavorings, we should be careful not to throw the baby out with the bath water. I believe that some in the e-cigarette industry have crossed over a line in promoting products with certain flavorings and affiliations. At the same time an adult smoker looking for alternatives to using the deadly combustible cigarette must be given products that are consumer acceptable, which includes taste. One thing that did not come out in the hearing was that nicotine replacement products (which contain nicotine derived from tobacco) have long had flavorings (fruit chill, lime, mocha etc.) in their products which are widely distributed, sold and marketed. There has been little to no adverse reaction to the use of flavorings in these products by either the public health community, Congress or regulatory agencies. Smokeless products also have certain flavoring allowances. There are important issues as to how and where lines get drawn and it will be incumbent on the FDA to set the appropriate *balanced* standards taking into consideration the risks, relative risks and intended uses of the products. The FDA, in cooperation with manufactures and other stakeholders should also monitor how products are being used and by whom so that adjustments might be made if there are unintended consequences. This would include flavorings.

(b) What is the risk that a ban on flavors would make switching away from combustion cigarettes relatively less appealing?

Answer. There are approximately 40 million smokers in the United States. Smoking is an addiction and the cigarette is the most efficient means of delivering nicotine. It is also the deadliest. Professor Michael Russell said it best back in 1976 when he said, “People smoke for the nicotine but die from the tar.” If smokers are going to be given options to quit smoking it is critical that the products that are available be consumer acceptable. This includes (among other things) that the product has acceptable tastes. Banning flavors outright would in my view discourage adult users of cigarettes from using significantly lower risk regulated products such as e-cigarettes—thereby undercutting public health objectives.

*Question 3.*

(a) Mr. Ballin, do you believe e-vapor products are as harmful as conventional cigarettes?

Answer. In terms of relative risk, no. E-cigarettes and e-vapor products are generally considered to be significantly lower in risk than the combustible cigarette. But we must also be very careful in assuming that all of these diverse products carry the same risk. The number of products in the marketplace has grown substantially and we have not gotten a handle on how to evaluate all these products and their variations. Yet there are good studies that have been conducted which confirm that many of these products are substantially lower in risk and could therefore be beneficial to public health—both to the individual and the general population. Using good science will be the primary responsibility of the FDA in setting product standards, and it will require the active involvement and cooperation of all stakeholders, including manufacturers. Additional and ongoing studies will also need to be conducted. Some manufacturers are developing products using scientific methods and manufacturing practices that are comparable to those used for foods or over-the-counter products while others are unfortunately producing products with far fewer scientific and manufacturing protocols.

(b) Would switching to an e-cigarette be a good thing for a consumer who was trying to quit smoking?

Answer. While the best recommendation is for a consumer to quit using all forms of tobacco and nicotine, it is increasingly becoming accepted that for those who cannot quit, there should be other alternative lower risk products available. While NRT products such as gums and lozenges have had some impact in helping smokers to quit, their success rate has been limited. Innovation, technological advancements and science are now making it possible to give consumers acceptable science-based lower risk products—including e-cigarette products. These efforts should be encouraged. That said we do need to have regulatory policies in place that include labeling, advertising and marketing allowances and which will provide consumers with the ability to understand the risks and relative risks of all of the various products in the market place.

(c) Is a combustible cigarette the same as an e-cigarette? If not, does it make sense for regulators, be it at the FDA or the states to be able to treat these products differently so that barriers are not created that would stop an adult smoker to switch to an e-cigarette?

Answer. As I indicated in my testimony before the Committee there is a growing recognition by many in public health, including the FDA, that tobacco and nicotine products should be regulated based on their *risk, relative risk and intended use*. This is often referred to as the continuum of risk. What this means is that products that cause the most harm and most risk (such as the cigarette) should be the most stringently regulating, while products further down the continuum of risk should have regulations tapered to reflect their risk. The FDA’s proposed deeming regulations have recognized the continuum of risk, and there is now general acceptance that e-cigarettes are not the same as a cigarette. Many have called e-cigarettes a “disrupting technology” that could significantly reduce the use of the toxic cigarette. For products that meet certain scientific criteria (product standards) I would suggest that rather than creating barriers to allowing these products on the market we should actually be providing incentives for manufacturers to continue to innovate and develop products that have the potential for moving more and more of the 40 million smokers off cigarettes. This was the approach suggested by the Institute of Medicine in its landmark report, *Clearing the Smoke*.

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