



Safe Kids Worldwide
Comment to the U.S. Food and Drug Administration on
Electronic Cigarettes and Liquid Nicotine
Docket No. FDA-2015-N-1514
September 30, 2015

Introduction

We applaud the Food and Drug Administration (FDA) for pursuing a rulemaking procedure regarding liquid nicotine because of the dangers it can present to kids and other vulnerable populations. Here, we focus on the danger to kids 19 and under. In this comment, we are joined by 21 Safe Kids coalitions around the U.S.

The Advanced Notice of Proposed Rulemaking (ANPRM) begins with the premise that liquid nicotine presents a danger for "acute toxicity" and there is a significant risk of inadvertent exposure to the substance involving infants and children. Liquid nicotine is a dangerous substance.¹ The American Academy of Pediatrics (AAP) says that a small (15mL) bottle of e-liquid contains a sufficient amount to kill four small children.² "One teaspoon of the liquid nicotine could be lethal to a child, and smaller amounts can cause severe illness, often requiring trips to the emergency department," warned the American Association of Poison Control Centers (AAPCC) in December 2014.³

The AAPCC made the foregoing statement after the first known death of a child from ingesting liquid nicotine. In December 2014, Eli James Hotaling, 18 months old, was being watched by Brenda Hotaling, his mother. Eli drank the contents of a vial of liquid nicotine from a 100 milligram vial labelled "Heartland Vapes," purchased online.⁴ Liquid nicotine is generally not sold in child resistant containers. The consumer could have made a separate purchase of a child resistant cap from the company, but she did not do so. The vial was left open on a low table in the dining room. The caregivers turned their back for an instant to look for a remote control and a SpongeBob SquarePants DVD, giving the toddler the time to drink the vial's contents. Eli began convulsing and was later pronounced dead in the emergency room of a nearby hospital. He died of cardiac arrhythmia.⁵

Thankfully, the Hotaling tragedy is the only report of a death involving a child in the U.S., but there is every sign that e-cigarettes and liquid nicotine will continue to grow in popularity. Calls to poison centers across the U.S. have increased by 1460%.

Some state legislatures have passed bills regulating liquid nicotine and e-cigarettes in various ways. However, the regulation of dangerous substances is traditionally and appropriately an area in which the federal government has acted to protect citizens on an across-the-board basis.

In Europe, regulation of e-cigarettes and liquid nicotine is stringent. Rules limit the amount of liquid nicotine to a dose that would be unlikely to cause death to a child. Childproof and tamper proof packaging is required, as are graphic warnings.⁶

We favor strong federal regulation in the U.S.

Safe Kids:

Safe Kids is a 28-year-old organization with the mission to prevent unintentional injury, the number one cause of death for children in the United States. The main risk areas in which we are involved are: home safety, risks in and around cars, consumer product safety, youth sports injuries and poisoning.

We are an organization with more than 400 coalitions in the United States and more than 25 partner organizations around the world. We have a presence in all 50 states and the District of Columbia. Close to ninety of the coalitions are based at children's pediatric hospitals and state and local health departments as well as at firehouses and police departments. They are on Indian reservations and near U.S. military bases. As stated earlier, 21 coalitions join us in this comment. We work closely with poison centers as we did in issuing our fourth research report on medications safety, "Medicine Safety for Children: An In-Depth Look at Calls to Poison Centers."⁷

We seek to meet our mission with committed involvement in research, education and awareness and advocacy for smart policy. Our work is based on a foundation of evidence.

Though unintentional injury remains the number one cause of death to children 1-19, we have made significant progress. The death rate from unintentional injuries has declined by 60% from 1987 to 2012.⁸

The diversity of our grassroots infrastructure gives us a unique first alert capacity to learn about emerging risks. The introduction of liquid nicotine and e-cigarettes to the marketplace--and to family homes--is one of those risk areas we have been monitoring, in part through the vigilance of our coalitions.

Liquid Nicotine and E-Cigarettes are the Kind of Products Which Invite the Natural Discovery Process of Young Kids

Kids, especially young ones, are natural explorers and their tools of discovery are their hands and mouth. When a child accesses a container of nicotine and drinks it, the likelihood of severe poisoning is strong. It is right, necessary and time to regulate liquid nicotine products relating to the need for:

- Child resistant packaging;
- Prominent, clear, easy-to-read, and easy-to-understand warning labels;
- A ban on marketing and advertising the product, just as with traditional tobacco products; and
- Education and awareness efforts to warn the public of the dangers of the substance and that parents and caregivers need to keep them "up and away" from small kids.

We understand that the FDA's jurisdiction is limited and some of what we see as necessary are policy initiatives that must be addressed by Congress. However, we urge the agency to exercise its full discretion to develop as broad a regulation as possible, and to do so in an expeditious fashion. Further, we hope the agency will take a long view and consider ways this risk may evolve and become an even greater risk to kids.

We will address several of the areas of inquiry in the ANPRM.

Safe Kids' Experience with Products and Substances that Can Lead to Poisoning:

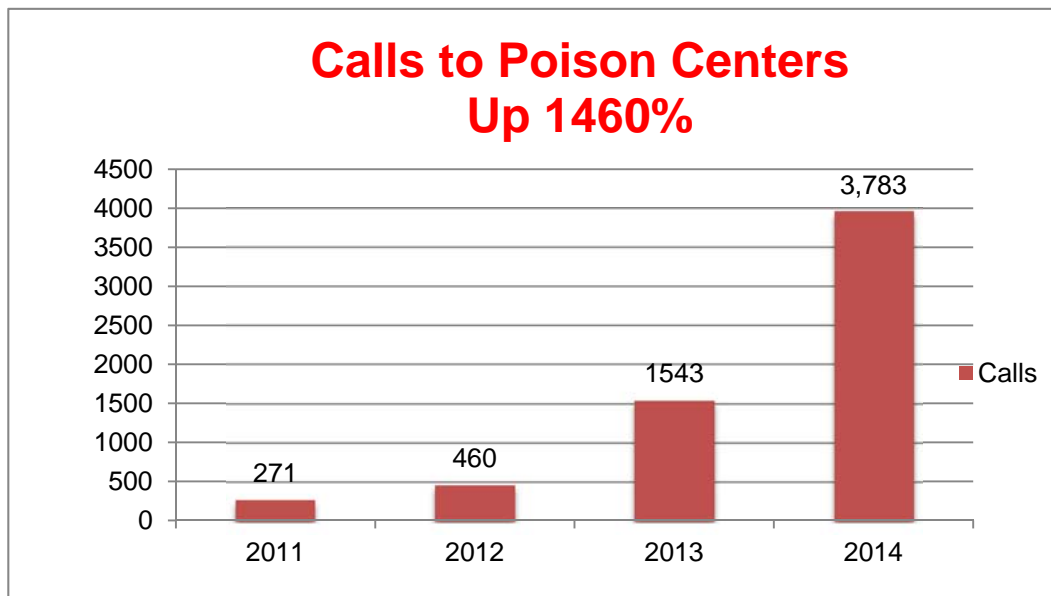
As stated earlier, children are curious and younger children in particular tend to put objects in their reach into their mouths. Safe Kids has an expertise in this aspect of child injury. In recent years, we have been involved in research, education/awareness and public policy relating to a diverse number of products in which swallowing creates severe problems:

- Small button batteries cause burning in the throat and esophagus when swallowed by a young child.
- A product once sold as a purported adult stress reliever consisted of small but powerful rare earth magnets. When a child swallowed a few of them they would clump together and cinch parts of young developing intestinal tracts sometimes requiring significant and serious surgeries.
- Medications left in a child's zone of discovery significantly increases their chance of poisoning.

Liquid nicotine in its vials or through its "e-cigarette" delivery devices are similar objects which can draw the attention of small children and create a strong risk of poisoning.

The Skyrocketing Calls to Poison Centers Support the Need for Strong Regulation

The chart below shows how calls to the U.S. network of poison centers have increased by 1460%.⁹ It is also of great concern that 51% of the poison calls involved children aged five and under according to the Centers for Disease Control and Prevention (CDC).¹⁰



Beyond Compelling Data, There Are Other Factors Requiring FDA Regulation

Data is important in making smart public policy and health best practices. The chart above states the case for strong and effective regulation by the FDA. It is crucial that the agency exercise the full extent of its jurisdiction in making this rule.

There are other factors suggesting the need for thorough and effective regulation:

1. **Big Business Getting Bigger:** The e-cigarette industry is worth nearly \$2 billion and is rapidly growing. It is estimated to be valued at more than \$10 billion a year industry within the next few years.¹¹ This will likely result in an increased exposure risk for children.
2. **Marketing Targets Youth:** The growing business has been using marketing tactics to make the product more attractive to younger consumers. The *USA Today* editorialized:

“While industry players repeat the mantra that e-cigarettes are *only* for adults, their marketing says the opposite. It includes the same sexy and rebellious images, celebrity users and pitches at sports and music events that helped addict generations of young smokers. E-cigarettes come in flavors such as Cherry Crush and Butter Crunch.”¹²

The Campaign for Tobacco Free Kids described the marketing efforts as follows:

“Despite the fact that nicotine is toxic, nicotine liquids used in e-cigarettes are sold in a rainbow of colors including ‘vivid vanilla,’ ‘cherry crush,’ chocolate, Jolly Rancher Gummy Bear and Bubble Gum.”¹³ There are an estimated 7,764 flavors of the substance.¹⁴ E-cigarettes have been marketed using the same tactics long used to market regular cigarettes to kids, including celebrity endorsements, slick TV and magazine ads, and sponsorships of race cars and concerts.¹³

In its scholarly journal *Pediatrics*, the AAP reported that youth exposure to e-cigarette marketing on television increased 256% between 2011 and 2013.¹⁵ On behalf of AAP, a pediatrician testified about the report to a U.S. Senate hearing on Aggressive E-Cigarette Marketing and Potential Consequences for Youth. She highlighted the pervasive nature of e-cigarette marketing towards young audiences.¹⁶

3. **It’s Working--Teens Switch Nicotine Interest:** The CDC recently reported in the National Youth Tobacco Survey that e-cigarette use among middle and high school students tripled from 2013 to 2014. Use of e-cigarettes on at least one day in a 30 day period among high school students increased from 4.5 percent in 2013 to 13.4 percent in 2014, rising from approximately 660,000 to 2 million students. This is the first time since the survey has been conducted that use of e-cigarettes surpassed current use of every other tobacco product overall, including conventional cigarettes.¹⁷ This increases the safety challenge for parents and caregivers of small children because the presence of the substance in the household will grow.
4. **Myths Fuel Interest in E-Cigarettes:** The “education” about e-cigarettes and liquid nicotine includes myths about the product. They include:
 - Liquid nicotine is pure and natural.
 - E-cigarettes are healthy.
 - E-cigarettes can help people quit smoking.
 - They eliminate the dangers of second-hand smoke.¹⁸
5. **Teens Using Liquid Nicotine in Innovative, Risky Ways:** There was a report in Washington state of high school students spiking sodas with the substance and drinking the new “cocktail” during class—they call it a “high.”¹⁹ While one of the myths about e-cigarettes is that it can help you

break the smoking habit, a study in *Pediatrics* reported that teens using e-cigarettes are more prone to take up smoking.²⁰

6. **E-cigarette Products Sold to be Stealthy.** There are “vape” products that can be used openly without letting on what the consumer is doing. E-cigarettes are being used to smoke marijuana, and enabling them to do it in an odorless, concealed manner.²¹ For example, discreetvape.com sells the “Puffit” vaporizer which looks like an asthma inhaler.²² A review in *The Cannibist* says, “The solution — *the one and only solution, of course* — is to be super sneaky when getting high in public.”²³
7. **E-Cigarette, Liquid Nicotine Price Point an Industry Advantage:** *The Wall Street Journal* observed that e-cigarettes are cheaper because they are unregulated and not taxed compared to traditional cigarettes with excise taxes, up to 50%.²⁴

The ANPRM seeks input on two areas, packaging and warnings. We are supportive of: 1) effective packaging to minimize the risk of poisoning, especially to vulnerable populations such as young children and teens; and 2) clear, visible and practical warnings about the risks and response if there is a dangerous exposure. The ban against advertising and marketing that has been in place for traditional cigarettes should extend to liquid nicotine and e-cigarettes. Another tool we must use to prevent poisoning and mortality is providing vigorous education and awareness about the dangers of liquid nicotine.

A. The Regulation Must Require that Liquid Nicotine is Packaged in the Most Effective Way, Including Child Resistant Containers, to Prevent Children from Exposure, Potential Poisoning and Other Dangers Such as Skin and Ocular Damage:

At present, liquid nicotine is sold in small vials with simple screw caps and sometimes in vials with a dropper. In a news story on Reno, Nevada’s KOLO-TV, a reporter demonstrated how easy it would be for “little hands” to open a liquid nicotine vial in an instant.²⁵ In discussing bipartisan legislation to regulate liquid nicotine, Senator Bill Nelson said the concentrated formulas of liquid nicotine are sold in “easy-to-open” vials that are “brightly colored” with “enticing flavors.”²⁶ Further, liquid nicotine is also contained in e-cigarettes, and can be opened by a child for ingestion.

The regulations should require that the products are sold in state-of-the-art child resistant packaging carefully enclosed and in a manner to accommodate effective warnings. The packages should at least meet the requirements of the Poison Prevention Packaging Act of 1970.²⁷

B. The FDA Must Require Thorough, Clear and Practical Warnings on the Packaging So That Parents, Caregivers and Others Understand the Risk and Know What To Do in the Event Of Exposure:

Because of the acute toxic nature of concentrated liquid nicotine, the effective packaging advocated above must be accompanied by prominent, clear, easy-to-read and easy-to-understand warnings. The two depend on each other. We recommend the following attributes for the warnings:

- The warnings must be clear, prominent and highly visible;
- They should be as specific as possible, rather than broad;
- The language should embrace best practices in medication literacy;
- It should include the toll free phone number for poison control centers—1-800-222-1222;

- It should address oral, ocular and skin exposure dangers;
- It should include the “up and away” message to “keep out of the reach of children”; and
- The use of child resistant packaging cannot eliminate the need for warnings.

We support the recommendations for content of the warnings in the comment provided by the California Poison Control Center System which include:²⁶

- Nicotine is a poison: Do not drink the liquid in this product
- Nicotine is a poison: Do not let the liquid touch your skin
- Nicotine is a poison: A single teaspoon of liquid nicotine is enough to kill a young child
- Nicotine is a poison, even in very small amounts.²⁶

We agree with the Center for Tobacco Control Research and Education at the University of California San Francisco (UCSF) that “The FDA should regularly update and refresh warning labels for maximum educational impact and to reflect the latest available information.”²⁸ Further, a challenge is that more and more language has a diminishing return because of “message fatigue.”²⁹ We recognize that this is a difficult balancing act.

B.1. The Warnings Must Go Beyond Poisoning and Caution Against its Use Because of the Addictive Properties of Nicotine, and Using E-Cigarettes:

The UCSF warnings start with this suggestion: “This product can cause and maintain nicotine addiction.”²⁶ The fact that risks associated with nicotine go beyond exposure and poisoning is important in what warnings are provided.

As the proposed warning states, nicotine is an addictive product. It is what makes the habit of cigarette smoking so hard to break.³⁰ While there remain questions about whether e-cigarettes lead to addiction as quickly or easily as when used in traditional cigarettes, the substance can lead to dependence.

An individual who is dependent on nicotine and/or is using e-cigarettes is exposed to a number of dangers.

- Nicotine can cause direct harm to cardiac muscle cells.³¹
- E-cigarettes release higher concentrations of formaldehyde, a known carcinogen, and other dangerous substances.³²
- Use can lead to significant central nervous system toxicity, and cause seizures and ataxia (negative impact on nervous system performance.)²⁹
- E-cigarettes deliver high levels of nanoparticles which can trigger lung inflammation and have been linked to asthma, stroke, heart disease and diabetes.³³
- E-Cigarettes may make bacterial infections resistant to antibiotics.³⁴

B.2. The Regulations Should Require the Warnings on Products Beyond Concentrated Liquid Nicotine:

Nicotine is highly dangerous regardless of its form, and the concentrated substance is more dangerous than a traditional cigarette. "It would be really hard for a child to eat a whole pack of cigarettes, but now we're dealing with these very, very concentrated forms you get more than a pack of cigarettes in a

small, ingestible amount," said Robert Bassett, a medical toxicologist.³⁵ The definition of the products requiring child resistant packaging and warnings should include "novelty" tobacco products, including e-cigarettes sold with the substance. Dr. Bassett consulted on a case involving a 10-month-old boy who had swallowed the substance. He was rushed to the emergency room and recovered. The boy was vomiting, his heart rate had sped up and he exhibited a loss of muscle control.³⁶

Furthermore, to reduce the risk of childhood poisoning, we recommend elimination of flavors that are attractive to young children and recommend that nicotine concentrations in e-cigarette liquids be limited to at least 2.4% (24 mg/mL). This level is similar to the 20 mg/mL limit proposed by the European Union for the sale of e-cigarettes.³⁷

C. The Marketing and Advertising to Attract the Attention of Young People Must Stop

Advertising for traditional nicotine/tobacco products has been banned on television and radio for 45 years.³⁸ In April 1970, an ad for Virginia Slims cigarettes was the last to air. The Family Smoking Prevention and Tobacco Control Act³⁹ went further by prohibiting tobacco companies from sponsoring sports, music and other kinds of cultural events. The agreement⁴⁰ ending the litigation against the tobacco industry went further still by barring outdoor, billboard and public transportation advertisements, as well as advertising aimed at kids.

We strongly support the Campaign for Tobacco Free Kids' call to action:

"The Food and Drug Administration must quickly finalize its proposed rule to regulate all tobacco products, including e-cigarettes, and stop the marketing and sale of these products to kids. Without FDA oversight, the irresponsible marketing of e-cigarettes threatens our nation's kids and health."

The statement was issued with examples of marketing campaigns aimed at a young audience. It included advertisements connected with its sponsorship of the "Smokin' Philadelphia" concert series that featured Imagine Dragons and Taylor Swift, performers attractive to a younger audience.⁴¹

In many ways, liquid nicotine has the potential to be a greater risk, especially on a short term basis, than tobacco. The same rules should apply.

D. The Federal Government Should Work With the Private Sector and Child Safety Non-Profits to Dramatically Increase Awareness about the Dangers of Liquid Nicotine and E-Cigarettes to Kids

Just as packaging and warnings can work together to decrease the threats to kids involving e-cigarettes and liquid nicotine, increasing public awareness is also an important factor. The CDC's "Up and Away and Out of Sight" campaign message has been found to be effective as a public-private partnership to keep medications out of the reach of kids.⁴²

The need for education and awareness involving the dangers of the liquid nicotine product were illustrated by the death of the first child from liquid nicotine poisoning. This is the case mentioned above in which caregivers had left an open vial giving 18-month-old Eli James Hotaling time to swallow the bottle's contents. The child died of cardiac arrhythmia.⁵

A child resistant container is not effective if a caregiver is not going to use the cap. The "up and away" messages that have been used to educate parents about the dangers of leaving medications, cleaning liquids and other dangers are necessary here.

An example of an awareness campaign in which Safe Kids was engaged involved the dangers of children ingesting medications within their reach. It drew from a research report, "Medicine Safety for Children: An In-Depth Look at Calls to Poison Centers."⁴³ Safe Kids' medicine safety campaign is made possible by our partner McNeil Consumer Healthcare. One of the partners in the effort was the CDC and its "PROTECT" campaign. The Safe Kids Medicine Safety for Children campaign, with multiple stakeholders, generated more than 670,000,000 media impressions in 2015 alone. Since the campaign launched, there was a 20% decrease in the number of poison center calls for children getting into medications.

While this was not within the scope of the ANPRM, Safe Kids feels strongly about the role of awareness campaigns in public safety policy making.

Conclusion:

The death of one child is one tragedy too many. The family of Eli Hotaling will never be the same in the aftermath of his death after drinking a small vial of liquid nicotine. We must use all of the tools that are commonly used in public health to prevent further losses, which include effective packaging and strong warnings. The educational process involving this risk must continue beyond warning labels to include public awareness campaigns. Finally, there should be a ban on advertising and marketing the product. We urge the agency to act using the full extent of its powers and to do so in an expeditious fashion.

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