

Liquid Nicotine Poisoning: An Emerging Threat to Children

Midwest Injury Prevention Alliance
Madison, WI

Kyran Quinlan, MD, MPH, FAAP
Chair
Council on Injury, Violence, and Poison Prevention
American Academy of Pediatrics



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INSIDE THE E-CIGARETTE



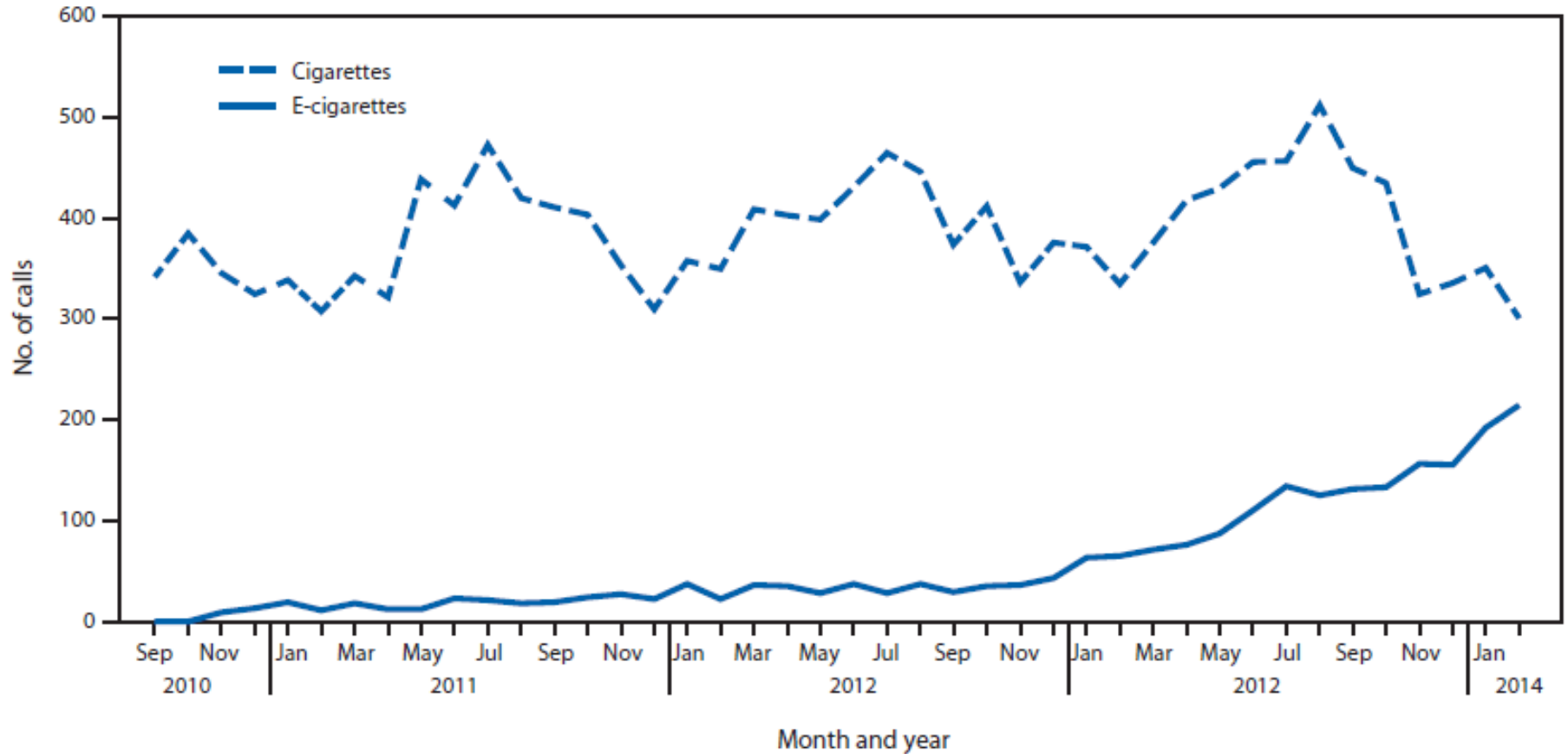


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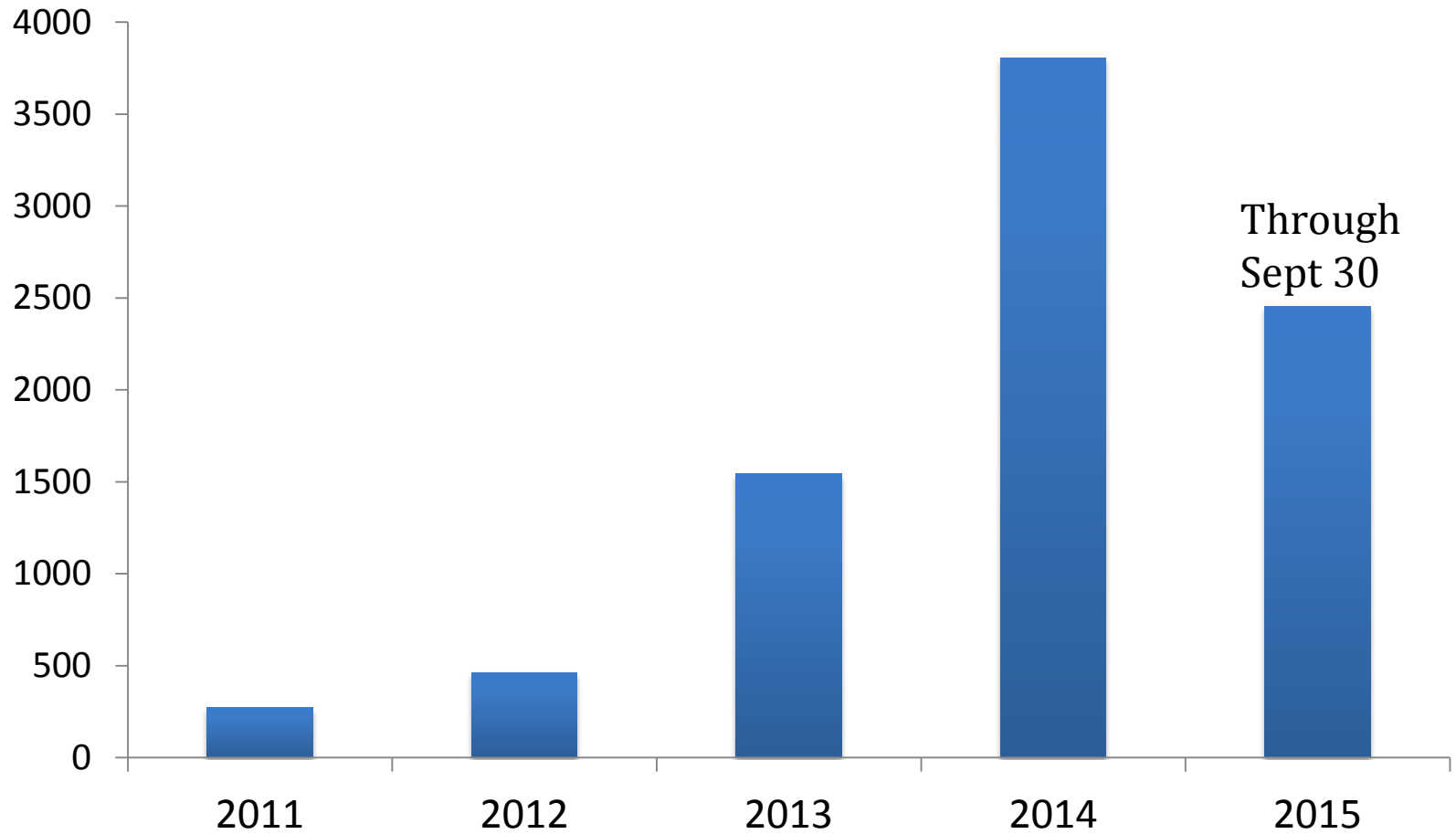
- Child poisoning with liquid nicotine a significant concern
- No current requirement for child-resistant packaging
- Serious poisonings of young children overall have been at historically low levels (source: CPSC)
- Over past 50 years, child poisoning deaths down from 400 to about 36 per year.



CDC MMWR- Calls to poison centers for cigarette or e-cigarette exposures, by month — United States, September 2010–February 2014



US Poison Control Center Calls



Children's Unique Vulnerability to Nicotine Poisoning

- Unintentional ingestions are highest among children under age five
- Normal development puts young children at risk of exposure
- Attractive packaging, colors and pictures



Children's Unique Vulnerability to Nicotine Poisoning

- Gross and fine motor development
- Many current containers of nicotine liquid easily opened by even young children
- Normal mouthing behaviors and appealing smells
- Young children naturally curious and lack awareness of consequences



Child Health Impact of Nicotine Poisoning

- High bioavailability with dermal exposure to liquid nicotine
- Toxic effects at much lower levels among the nicotine-naïve
- The LD50 of nicotine not precisely known but probably 1-13 mg/kg



Nicotine poisoning in a 10-month-old boy

After ingesting a “small”
amount of e-liquid nicotine
from a hand-labeled bottle

Vomiting

Tachycardia

Grunting respirations

Truncal ataxia



LD50 for 10 kg 1-year-old

Concentration	LD50 1-13 mg/kg	Common units of upper limit
18 mg/ml	0.6-7.2 ml	< 1½ tsp
24 mg/ml	0.4-5.4 ml	1 tsp
36 mg/ml	0.3-3.6 ml	< 1 tsp



Albany Times Union December 9, 2014

FORT PLAIN - A 1-year-old boy died Tuesday after, police said, he swallowed liquid nicotine, the chemical used in electronic cigarettes.

Emergency workers were called to a home on Garfield Street at 4:06 p.m. Tuesday after getting a call that a child was "unresponsive."

Need for Action

- First U.S. child fatality in December 2014, in a one-year-old boy in Fort Plain, NY
- One child fatality reported in Israel (May, 2013)
- Lack of child-resistant packaging leaves children as our early warning system
- We must act now to prevent future exposures and potential deaths



Need for Action

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Success in Preventing Child Poisoning

- Success of the Poison Prevention Packaging Act (PPPA)
- PPPA special packaging requirements have prevented an estimated 900 child deaths since taking effect in the 1970s
- The PPPA prevented 24 child deaths annually from oral prescription drugs between 1964 and 1992
- Special packaging has reduced aspirin-related mortality rate 34 percent, preventing 90 child deaths between 1973 and 1990.



Prevention Strategies

Require child-resistant packaging

Limit mg of nicotine per container

Require flow restrictors



Federal Regulation



Regulatory void

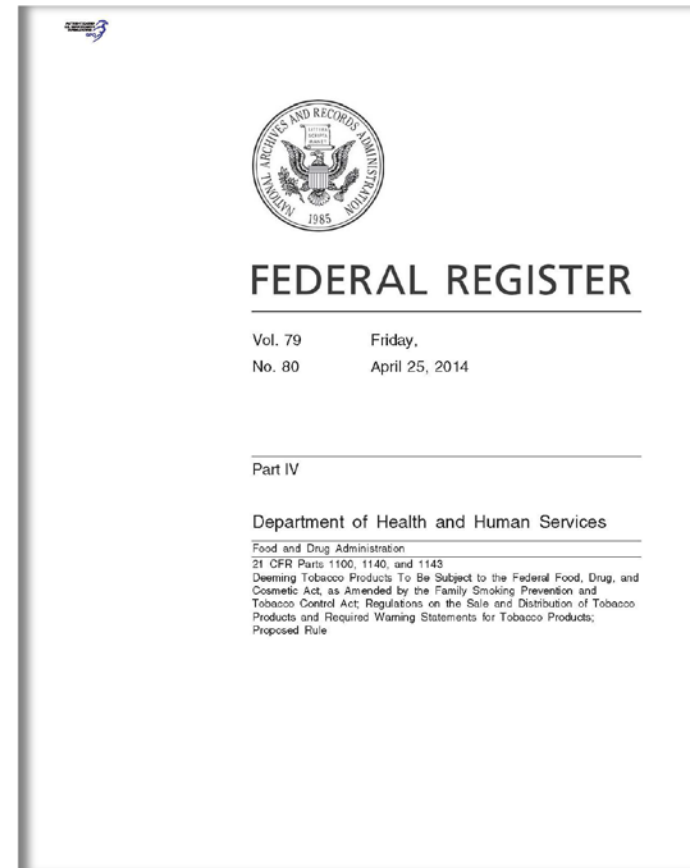
- FDA tried to regulate e-cigarettes as nicotine delivery device.
- Industry sued FDA. Industry won.
- Judicial system determined e-cigarettes are a tobacco product.

Regulation of tobacco products

- FDA regulates tobacco products, but must request regulatory authority from Congress for e-cigarettes
- FDA filed paperwork, but did not include child-resistant packaging
- Even after getting regulatory authority, FDA does not regulate child-resistant packaging.

Need for a Legislative Solution

- CPSC authority under PPPA exempts tobacco products
- No child-resistant requirement in deeming regulation
- FDA ultimately has authority but FDA process may take years
- Need to act now to prevent further exposures and deaths
- Well-trod path for cooperation between CPSC and FDA on prescription drugs



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FDA CTP Workshop:
Electronic Cigarettes and the Public Health
December 11, 2014

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FDA

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

EXIT

Regulatory Action

- FDA published ANPRM in July 2015
- Asked for comments on child-resistant packaging and nicotine exposure warnings
- AAP and 43 other groups urge quick FDA action:
 - FDA has clear authority
 - FDA should take urgent action on child-resistance and warnings
 - FDA should consider other issues including: flavors, colors, pictures, quantity/concentration, devices





Recommendations from 43 groups

child-resistant packaging for liquid nicotine containers consistent with existing standards established and overseen by the U.S. Consumer Product Safety Commission (CPSC)

nicotine exposure warnings on liquid nicotine containers that specifically describe the risks to children, including injury and death

Children cannot wait

- FDA process may take 2 years
- Children at risk now
- Sen. Nelson (D-FL) introduced bill to give authority to CPSC to oversee child-resistant packaging of liquid nicotine

Child Nicotine Poisoning Prevention Act of 2015

- Does not alter underlying tobacco exemption on CPSC
- Targets liquid nicotine containers
- Does not affect disposable e-cigs or those with self-contained refill cartridges
- Supported by some industry groups, including the Smoke-Free Alternatives Trade Association and the American Vaping Association
- Preserves FDA authority



July 11, 2014 13:14 ET

Smoke-Free Alternatives Trade Association (SFATA) Comments Regarding Senator Nelson's Bill on Child-Resistant Packaging for E-Liquid Used in Vapor Products

WASHINGTON, D.C.—(Marketwired - Jul 11, 2014) - SFATA, the largest trade organization dedicated to the commonsense self requirement for mandatory use in ingestion of nicotine

"Though the inc-
common househ
consumption by
SFATA Executive
the industry safe
indispensable al

For more in form

FOR IMMEDIATE RELEASE



American Vaping Association Supports Sen. Harkin's Effort to Childproof E-Cigarette Products

WASHINGTON, D.C., July 14, 2014 – The American Vaping Association (AVA), a leading advocate for the health benefits of electronic cigarettes, today endorsed legislation by Sen. Tom Harkin (D-Iowa) and others that would require child-proof packaging for liquids used in e-cigarettes.

"Sen. Harkin's legislation aligns with the mission of the e-cigarette industry: to create safer products that further the government's goal of reducing tobacco-related disease and death," said Gregory Conley, AVA's president. "E-cigarettes help smokers quit the tobacco habit, but they aren't for children. We urge Congress to pass common-sense laws like Sen. Harkin's that make clear that e-cigarettes are not a child's play."

In addition to backing Sen. Harkin's legislation, the AVA supports a federal ban on the sale of e-cigarettes to minors. Forty-one states already have such a ban on the books.

The Food and Drug Administration is proposing to classify e-cigarettes as tobacco products. The AVA believes that rule would unnecessarily burden the fast-growing, U.S.-based e-cigarette industry with complicated and expensive regulations. The AVA has called on the FDA to extend its period for public comment about the classification for another three months beyond its current August 8 deadline.

The AVA is concerned that the proposed FDA rules would essentially hand over the e-cigarette market to Big Tobacco at the expense of consumers, public health and small- and medium-sized e-cigarette businesses. The AVA represents independent manufacturers in the e-cigarette industry, many of which are family-owned and operated in the U.S.

Read AVA's action alert here: <http://vaping.info/ava-act-on-alert>

You can learn more about AVA and vaping by visiting the AVA [website](http://www.ava.org).

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Child Nicotine Poisoning Prevention Act of 2015

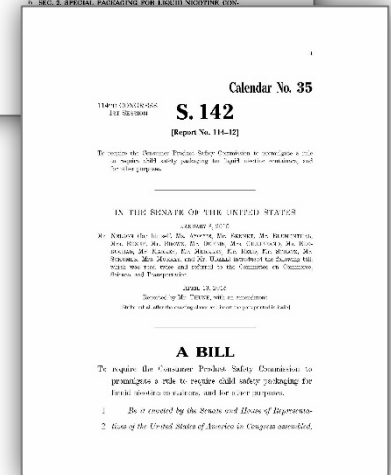
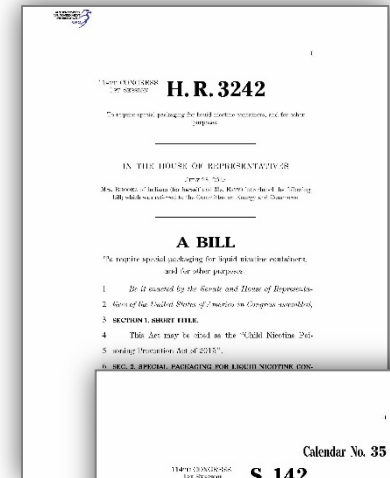
- S. 142/ H.R. 3242
- Provides CPSC narrow authority to issue a rule within 6 months
- Would require “special packaging” for liquid nicotine
- Bipartisan in the Senate- Bill Nelson (D-FL) and Kelly Ayotte (R-NH)
- Senate and House Committee approved



Legislative Action



- Child Nicotine Poisoning Prevention Act of 2015
- Designed to address urgent hazard
- Requires liquid nicotine containers to meet PPPA child-resistant packaging standard within 6 months
- Preserves all FDA authorities under Tobacco Control Act, deeming, ANPRM
- If passed, FDA and CPSC must work together



Child Nicotine Poisoning Prevention Act of 2015

- House and Senate Bills need to be passed.
- Then reconciled.
- Then signed by Obama.



State E-Cigarette Liquid Packaging Laws



Spring
2015



Last
week in
Chicago



Last
week in
Chicago



Conclusions

- Liquid nicotine is a new poisoning risk and can kill
- Unique federal regulatory void
- States rapidly trying to respond
- Enforcement of state laws
- Awareness and vigilance





<http://bestjuiceusa.com/smr-product/kaptain-krunch-peanut-butter/>.



<http://www.affordablevapor.com/gummy-bears-e-liquid.html>



<https://www.hookah-shisha.com/p-18106-cali-vape-grape-bubble-gum-e-liquid-18mg.html>



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