

# **Child resistant packaging of electronic cigarette devices and refill liquid containers containing nicotine to prevent childhood poisoning**

**Docket No. FDA-2014-N-0189**

**California Poison Control System**

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This comment is being submitted on behalf of the California Poison and Control System (CPCS), which handles calls related to potentially harmful exposures to drugs and toxicants throughout the state of California. The CPCS strongly recommends that all electronic cigarette devices and refill liquid containers be required to be child resistant in accordance with the Poison Prevention Packaging Act of 1970. We also recommend that flavors such as fruit and candy that are especially attractive to young children be banned, that nicotine concentrations in e-cigarette liquids be limited, and that health warnings include the statement that the product may cause serious harm to children. Such regulation is needed urgently to protect children.

Nicotine sustains tobacco addiction, and self-administration of nicotine is the primary reason why people use conventional as well as electronic cigarettes. Nicotine in low doses has primarily stimulant effects on the brain, but in high doses nicotine disrupts central nervous system functioning and is a deadly poison.<sup>1,2</sup>

The typical systemic delivery of nicotine to a smoker from smoking a cigarette is 1mg. The tobacco of one cigarette contains 10-15mg nicotine. Childhood ingestion of cigarettes is not uncommon, but because nicotine is mixed throughout the tobacco and is absorbed slowly, and tobacco ingestion usually causes vomiting, most of the tobacco and nicotine is vomited up before serious poisoning can occur.<sup>3</sup>

The use of electronic cigarettes by an experienced user also delivers a systemic dose of about 1mg nicotine during a typical session, similar to that delivered by cigarette smoking.<sup>4</sup> However, the liquid used in e-cigarettes consists of a highly concentrated nicotine solution. Concentrations of nicotine in e-liquids used in e-cigarette devices may be as high as 3.2% (32mg/ml), but some refill solutions can be purchased on the Internet with concentrations as high as 10% (100mg/ml). A typical nicotine concentration in an e-liquid would be 2.4% or 24mg/ml. A typical e-cigarette contains about 1-3ml liquid which means that it contains up to 72mg of nicotine. A 30ml refill vial of 2.4% contains 720mg of nicotine. A 30ml vial of 10% nicotine would contain 3000mg of nicotine.

Nicotine in high concentrations, either when ingested or with skin exposure, can result in serious or fatal poisoning.<sup>3,5</sup> Symptoms of toxicity include nausea, vomiting, seizures, coma, cardiovascular instability, respiratory arrest and sometimes death. The lethal dose of nicotine in

a human has been debated, but is thought to range from 1-10 mg/kg.<sup>6</sup> The nicotine content of many refill vials would be seriously toxic to an adult. Of even greater concern is accidental exposure by children, who are much smaller so the same dose would have much more of an effect. A toddler weighing 10kg could be severely poisoned by the ingestion of the nicotine in a single EC device. A recent case report describes such a poisoning in a 10 month old child.<sup>7</sup> A case series from the CPCS reported 35 cases, including 14 children, with potentially toxic e-cigarette exposures. Another particular concern is that many e-liquids are flavored with candy or food flavors that are highly attractive to children.<sup>8</sup>

Poison control centers nationally have received a rapidly escalating number of calls regarding possible harmful effects of e-cigarette exposure. The CDC reported more than 2400 calls to poison centers between December 2010 and February 2014.<sup>9,10</sup> The number of calls per month increased from one call per month 2010 to 215 per month in 2014. The CPCS has had a similar increase in calls, from 2-3 calls per month in California in 2012 to 12 calls per month in the past year. About 40% of calls resulted in emergency room referrals. To our knowledge there have been no deaths in children due to electronic cigarette exposure in the U.S., but there have been in other countries.

The California Poison Control System strongly urges regulation of electronic cigarette devices and refill fluids to ensure that they be child resistant and that health warnings include the statement that the product may cause serious harm to children. Furthermore, to reduce the risk of childhood poisoning, we recommends elimination of flavors that are attractive to young children and recommend that nicotine concentrations in e-cigarette liquids be limited to a maximum of 2.4% (24 mg/ml). This level is similar to the 20 mg/ml limit proposed by the European Union for e-cigarettes that can be considered as tobacco products.

## References

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