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Electronic cigarette device-related hazards: a call for immediate FDA regulation

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Modern electronic cigarettes (e-cigarettes), first patented in 2003 as an alternative to tobacco cigarettes, have been widely available in the United States since 2006.¹ E-cigarettes are devices that convert a liquid solution typically consisting of an excipient (propylene glycol and/or vegetable glycerol), flavorings, and nicotine into an aerosol that users inhale.¹ E-cigarettes have been touted as a safer alternative to deadly tobacco cigarettes, and have gained favor as a potential substitute for tobacco cigarette smoking.^{2–5} In fact, while tobacco cigarette use is decreasing in high school students, e-cigarette use is soaring, since many young people view them as harmless.⁶ Nonetheless, concerns remain regarding the long term safety of e-cigarette use, since the long term health effects of inhaling e-cigarette aerosol are unknown. Importantly, an immediate concern, which *is* already apparent - *and correctable* - is the danger inherent in several features of the e-cigarette devices themselves.

E-cigarette devices are composed of three key elements: a cartridge that holds the liquid solution, an atomizer or heating element that converts the liquid into aerosol without combustion, and a battery.⁷ At the time of this review, the major concerns about the safety of the devices fall into two categories: 1) *Poor device workmanship* which may lead to the potentially injurious release of metal particulates from the device into the inhaled aerosol,^{8–11} and actual device explosions due to inferiorly fabricated batteries,^{12–16} or 2) *Unlimited device heating capacity*, resulting in overheating of liquid constituents and the generation of carcinogens.^{7, 17, 18} With the recent release of Food and Drug Administration (FDA) regulations, strict sales regulations will soon take effect, and producers of solutions to be aerosolized will be required to satisfy certain safety standards.¹⁹ However, these new regulations will only partially offset the present and known hazards inherent in the e-cigarette devices themselves. It is important to recognize these well-documented e-cigarette device-related hazards, which may be correctable through industry standards, so that future device-related complications can be minimized and even eliminated.

Poor or careless metal workmanship, including shoddy soldering, has been identified in commercially available e-cigarettes. Several studies have reported the presence of metal particulates in e-cigarette aerosol that were not present in the unheated liquid. Williams and

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colleagues detected levels of aerosolized metals and silicates in e-cigarette aerosol that were equal to, or in some cases actually exceeded, those levels found in tobacco cigarette smoke.⁸ Black debris was present on fiberglass wicks, from which silicate microparticles were released.⁸ Using scanning electron microscopy to study the used devices, these investigators found areas where absent silver coating left exposed the copper wire beneath; at poor quality solder joints, tin “whiskers” were present from which metal particulates were released. This hazard could be ameliorated by coating the copper wiring with silver rather than tin, and by using brass clamps and/or brazing rather than soldering. Additionally, the stable solder joints ideally would be placed outside the atomizing chamber.¹¹ Lerner et al found copper levels in the aerosol of one e-cigarette brand 6.1 times higher per puff than conventional cigarettes.⁹ Another Lerner study described significant increases in the level of mitochondrial reactive oxygen species, DNA fragmentation, and inflammatory cytokines in cells treated with copper metal nanopartilces an e-cigarette aerosols.²⁰ In a recent review examining metal levels in e-cigarette aerosol from 13 different e-cigarette products, it was reported that the equivalent daily exposure of cadmium exceeded safe levels, although in general, the presence of other metal particulates did not exceed the acceptable upper limit.¹⁰ Given that excessive inhalation of metals can produce adverse health effects,²¹ their presence in e-cigarette aerosols must be addressed by the FDA and e-cigarette manufacturers. Aerosolized metal exposure from e-cigarettes could be largely eliminated if minimal e-cigarette device manufacturing standards were established - and maintained.

The most extreme and immediate hazard posed by e-cigarette devices is the well documented risk of spontaneous explosions leading traumatic injuries and/or fire. Three instances of spontaneous e-cigarette device explosions were described in one medical case series. One man suffered facial lacerations and tooth fractures when the device exploded in his mouth, while the other two individuals required skin grafting for third-degree burns after the devices exploded in their pockets.¹² Another case report from the UC Irvine Medical Center documented the injuries sustained when an e-cigarette device exploded. Small particle shrapnel from the explosion struck the e-cigarette user in the left hand and arm, left shoulder, upper abdomen, and chest.¹³ In another report, the oral trauma and tooth avulsion from the explosion of an e-cigarette device in the user’s mouth were detailed.^{14, 22} The lithium ion battery, used in many e-cigarette brands, carries the benefits of potency and duration of charge, but is susceptible to extreme increases in internal temperature causing the battery to ignite or even explode. Lithium batteries that are poorly manufactured using inferior materials are especially vulnerable to this dangerous condition called “thermal runaway.”⁷ According to a 2014 United States Fire Administration report, 25 separate incidents of explosion and fire involving an e-cigarette were reported in the U.S. media between 2009 and August 2014. Of these, 20 (80%) were confirmed to occur while the device was charging. At least 22 incidents led to some degree of fire, the largest of which destroyed a bedroom. Given that many of the failures occurred while the battery was charging with power supplies that were not provided by the manufacturer, e-cigarette manufacturers should consider changing to a unique and otherwise incompatible style of electrical connection, incorporating protection circuits into the devices, and improving battery casings and design.¹⁶ Explosions and fires have been observed frequently enough that the US Department of Transportation has banned e-cigarette devices in checked baggage

aboard airplanes.¹⁴ The new FDA e-cigarette regulations do not yet specify minimal standards for lithium ion batteries in e-cigarettes; this lapse in proposed oversight allows the presence of a known and correctable hazard in e-cigarette design to persist.

A third e-cigarette device-related hazard stems from the potential for excessive heating of the otherwise stable e-liquid. By manipulating the heating element features, including resistance and voltage difference, extreme temperatures can be reached. Extreme temperatures may adversely affect the aerosol, generating significant levels of toxic constituents, and alterations in particle size. The e-cigarette user can modify the heating element features of the 3rd generation e-cigarettes, leading to their nickname, “Mods.” Propylene glycol, a common excipient used in the liquids, can form volatile carbonyls including formaldehyde (an International Agency for Research on Cancer group 1 carcinogen), acetaldehyde, and acrolein at high temperatures, all known to be toxic at sufficient concentrations. A sharp increase in the amount of carbonyls occurs when atomizer temperatures exceed 200–250°C, corresponding with 15 Watts or more of battery output, well within range on most Mods. It is important to note that the aldehyde levels emitted from tobacco cigarettes are anywhere from 2 to 2100 times higher than from 1st or 2nd generation e-cigarettes in which these heating element parameters are pre-set, and not modifiable.¹⁷ However, levels of formaldehydes emitted from these modified e-cigarettes have the potential to exceed those emitted from conventional tobacco cigarettes.¹⁸ The recently introduced FDA regulations do not include limits on heating element material, temperature, or voltage – limits that have the potential to save lives.

The proposed FDA regulations of the e-cigarette devices are insufficient to protect users from the real and present hazards of poor device workmanship and potential to reach supra-high temperatures. The proposed package warning label, (“This product contains nicotine. Nicotine is an addictive material.”) focusses on the liquid, but does not include sufficient warning about the delivery system,¹⁵ such as the rare but devastating risk of battery explosion.¹⁶ While e-cigarettes show promise as a less harmful alternative to conventional smoking, as currently designed they pose serious and unnecessary safety concerns. Furthermore, there may be additional risks associated with e-cigarette use that have yet to be identified. Continued monitoring of the hazards and long-term effects of e-cigarette use, and the FDA’s ability to address new information as it becomes available, are critical to optimizing public safety with respect to these devices. With adequate oversight and regulation of e-cigarette devices, serious injury from explosions and exposures to harmful compounds can be mitigated or even eliminated. The recent FDA regulations offer only a small step in the right direction toward necessary oversight, regulation, and safety of e-cigarette devices, whereas the current scientific knowledge supports a bold, giant step.

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