

As US vaping-related lung illnesses soar, FDA found negligent in enforcing e-cig regulations

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7 October 2019

According to the Centers for Disease Control and Prevention (CDC), as of October 1 there have been 1,080 cases of lung injury arising from e-cigarette (e-cig) use, up from the 450 cases confirmed in early September. Casualties have been documented in 48 states and 1 US territory, the US Virgin Islands. Eighteen deaths have been confirmed in 15 states. According to an October 3 *New York Times* report, additional deaths have been cited in a total of 16 states. This is an increase from five reported deaths a month ago.

The recent explosion of cases over the last two to three weeks includes a combination of 275 new cases as well as prior unrecognized cases of unusual pneumonia-like illnesses that have now been reclassified lung injuries caused by vaping. The CDC has reported more than 3.6 million adolescents in the US have used e-cigs.

A report issued by the NIH's drug abuse section highlights the dramatic rise in vaping among teenagers; 37.3 percent of 12th graders reported they had vaped in the past 12 months. The prevalence of vaping among teenagers in 2011 was near zero. By 2017 it had become the most common use of any tobacco-like product in this age group. The number of adolescents vaping in 2019 is double that in 2017.

In the cohort of people with lung injuries, each affected individual has reported having vaped within the month of falling ill and most note using products containing THC, the principal psychoactive constituent of cannabis. The CDC and medical officials believe THC has played a role in the outbreak.

The exact chemical compound causing these illnesses remains elusive at present. The CDC remarks, "No single product or substance has been linked to all the lung injuries." Seventy percent of those affected are

male, and 80 percent are under the age of 35. One-third of them are under the age of 21 and 16 percent under the age of 18, the cut-off ages for the legal sale of e-cigs depending on the state.

In a recent publication in the *New England Journal of Medicine* (NEJM) this month, the Mayo Clinic reported their findings on lung tissue biopsies from 17 subjects, 11 of which met CDC criteria for a confirmed diagnosis of vaping-related lung injury. According to their findings, the injuries resemble those that occur with inhalation of noxious chemical fumes, suggesting a similar mechanism of injury.

The CDC noted several THC-related products that were used by patients in Illinois and Wisconsin before they became ill, which include Dank Vapes, Moon Rocks, Off White and TKO.

In her testimony to the subcommittee of the House Energy and Commerce Committee on September 25, Dr. Anne Schuchat, principal deputy director of the CDC, said, "There are a complex set of root causes at play here that will be difficult for us as a nation to address. We need to take it very seriously. There are a set of supply chains that are underground that are adulterating the products in ways that are just experimental that are building on a population that is addicted to e-cigarettes. We have a very vulnerable population and a very challenging difficult supply chain we need to address."

As the initial study published in the NEJM in September noted, all patients suffer from profound weakness and shortness of breath. They require hospitalization and supplemental oxygenation. Many are treated in the intensive care unit, and some have significant lung injury necessitating ventilator assist to breath. Some are placed on cardio-pulmonary bypass to oxygenate their blood while their lungs have time to

heal. Most have recovered and are sent home after a few days or weeks. The long-term impact on their lung function remains to be determined.

The initial knee-jerk response by several states has been to order a ban on the sale of flavored e-cigs, which are popular with adolescents. Massachusetts has banned all vaping products. Several vaping groups have filed lawsuits against the proposed bans, contending they will unduly hurt retailers as well as adults who use the products as an alternative to cigarettes.

The FDA has recently been the target of an inquiry by US Congress members for their lax enforcement of these products as a means to calm the public over their long-standing negligence. According to the *Boston Globe*, “It took the Obama administration seven years, from when the FDA received authority over tobacco from Congress in 2009, to rule that e-cigarettes were also under the agency’s purview.” FDA officials cited difficult regulatory processes for these delays, including interference by industry lobbyists. Included in those proposals were restricting flavored e-cigs due to their appeal to young people, but this was deleted according to records.

Despite finally expanding their regulations in 2016 that required manufacturers submit applications for e-cigs and related products within two years, they again neglected their duties, as the former commissioner of the FDA, Scott Gottlieb, told NPR, “out of an exercise of enforcement discretion.” The deadline was moved back to 2022.

A lawsuit brought against the FDA in the District of Maryland found in May that the FDA had exceeded its legal authority, “giving manufacturers responsible for public harm a holiday from meeting the obligations of the law.” The FDA has now issued new guidance that manufacturers have until May of 2020 to submit their applications if they are to continue selling their products.

The US e-cigarette market was worth \$11.26 billion in 2018 and is projected to reach \$18.16 billion by 2024. E-commerce and online retailing have emerged as new distribution channels for these products, increasing accessibility for underaged people.

The supposed purpose of vaping was to provide a new nicotine delivery mechanism to help smokers wean off combustible tobacco. There are potent nicotine salts in e-cig pods and liquids that can deliver a massive

nicotine surge that allows an even higher peak concentration of nicotine in the blood than combustible tobacco to soothe cravings. What was designed to possibly help tobacco addicts quit smoking has essentially created a new addiction in young people whose ramifications are barely understood.

Europe is presently the largest market in the world for e-cigarettes. Traditional tobacco companies like UK British American Tobacco PLC and Imperial PLC are investing billions into developing an alternative to traditional smoking. France is distinguished as the largest e-cigarette market, with over 500 shops dealing in such products. Presently, there are no outbreaks of vaping-related lung illnesses reported there. One case cited in the UK in June 2019 had similarities with the US cases diagnosed as lipoid pneumonia. Physicians suspect that vaping liquid was to blame for the patient’s illness.



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