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The need to more effectively regulate END markets: A primary public health lesson of the U.S. vaping associated lung injury outbreak

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The hesitation of CDC scientists regarding the role of a single ingredient, presumed to be contained only in illicitly sold cannabis products, may not reflect confirmation bias but rather an appropriate skepticism regarding the presence of that ingredient in products being sold in legal markets as well.

The article by Hall et al [1] provides a very useful historical timeline of the key events surrounding the outbreak of lung injuries in the United States in 2019. It documents the hesitancy of the US Centers of Disease Control (CDC) to conclude from early evidence that the cause of the outbreak was illicit cannabis oils contaminated by vitamin E acetate. The article concludes that the CDC was displaying confirmation bias in their evaluation of the evidence. Such an assessment may be unfair when viewed within the context of the uncertain safety of products being supplied in the US e-cigarette and nicotine delivery (END) market.

Although the authors acknowledge that regulation of END products differs considerably across countries, they do not fully describe the implications for the supply side of the market. There are many. To begin, the designation of END products as “tobacco products” rather than “medical products” in August 2016 meant manufacturers did not have to meet pharmaceutical safety standards; instead, minimal product safety regulations were imposed [2]. Manufacturers only had to report ingredients of finished tobacco products to gain approval from the Food and Drug Administration (FDA) to join the market, but products already on the market were granted time, ultimately until August 2022, to comply [3 4]. Regulations requiring disclosures of ingredients of all e-liquid contents did not get announced until November 2018 [5]. When enforcement of these and other regulations occurred, it was minimal [3,6]. Thus, the setting was laid for the existing unregulated US END market to continue, and expand, under a weak system that allowed END products with unknown ingredients and additives to be legally sold.

Other unique features of supply in the United States contributed to the uncertainty around ingredients within legal END products. Unlike the cigarette market, where smokers have substantial brand loyalty and purchase established products from traditional retail settings (e.g. convenience stores), the US END market is highly competitive with lots of independent small and large manufacturers selling online and through specialty retail outlets [3]. Vape shops, which sell disposable END products, closed reusable systems, and open reusable systems, as well as the pre-filled cartridges, refill products, and their own mixtures of e-liquids that can be vaped from them, are the main retail source of END products [7,8]. Vape shops' role in mixing and distributing their own e-liquids has only recently gained the attention of the FDA [9], and it compounds the existing uncertainty regarding the actual contents and safety of e-cigarette liquids given the lack of ingredient oversight [10,11].

Medical and legal cannabis in many US states has led to the further proliferation of new END products [12,13] not subject to FDA regulation because of the federal prohibition. Cannabidiol (CBD) oils, for example, are commonly sold in vape shops, even in states that have not legalized cannabis. An audit of vape shops in six major metropolitan areas in 2018 found that 42.5% sold e-liquids containing CBD; they were even more common (present in >60%) in areas where cannabis was illegal [7]. An investigation of the chemical contents of 30 CBD vape products sold in vape shops across the United States found that one-third of the products contained variations of synthetic cannabis and other potentially harmful chemicals, including a popular pod product that was compatible with Juul electronic cigarettes being sold in 3 states [14].

The lack of early documentation of ingredients of legal END products [5,6], the unreliable labelling of products [10,14], and the sale of both nicotine infused and cannabis-based e-liquids in ubiquitous vape shops [7] may have reasonably contributed to the hesitation of CDC scientists when drawing conclusions from a 2% convenience sample of identified vaping-associated lung injury cases that it was vitamin E acetate from illicit THC products that was the primary culprit [15]. A market that ensures the safety of a product through careful regulation with enforcement, regular and consistent testing of ingredients, and restrictions on promotion for non-intended use would enable quicker conclusions to be drawn.

Skepticism of the public health benefit of END products in the United States is clearly high, but not without cause. Juul products in the United States contain three times the liquid nicotine concentration than the same Juul product sold in Europe [16] and END manufacturers in the United States continue to develop and aggressively market stealth vaping delivery devices, resembling USB sticks, pens, asthma inhalers, and even car fobs that can be hidden in hoodies and backpacks [17,18]. These are not practices that companies selling other smoking cessation devices follow.

Declaration of interest

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