

### 3. Draws on irrelevant information about an outbreak of lung injuries in North America.

**The EVALI lung injury outbreak is irrelevant.** Rather than accept overwhelming evidence for greatly reduced risk, the justification draws on the 2019 outbreak of “EVALI” (E-cigarette and Vaping product Associated Lung Injury) in the United States, though notes that there have been no cases in the Netherlands. This section is a distraction. EVALI is a misnomer and relates to the contamination of the supply of illicit cannabinoid (THC) vape pens in the United States with a cutting agent, Vitamin E Acetate. This agent is added to the viscous oily excipient used for THC liquids.<sup>1</sup> This agent cannot be added to nicotine e-liquids and would serve no economic purpose because nicotine e-liquids can be diluted easily and cheaply with standard diluents, propylene glycol and glycerol. The EVALI outbreak was largely contained within North America, and it emerged in mid-2019 and had largely disappeared by February 2020.<sup>2</sup> The pattern is consistent with an episode of supply chain adulteration. Once Vitamin E Acetate was identified as a cause, there is a vanishingly small chance of any other independent cause arising in the same limited geography, causing the same symptoms, and appearing and disappearing at the same time.

**Vague references to severe lung conditions in vapers do not form a basis for regulation.** Having failed to show EVALI is relevant to the Netherlands or to nicotine vaping, the justification pivots to assertions from a Trimbos fact sheet<sup>3</sup> claiming Dutch pulmonologists have seen other lung injuries, which in turn references a news article about some pulmonologists calling for a ban on e-cigarette, claiming lung cases had risen from three to eight.<sup>4</sup> This is a poor articulation of evidence for policymaking purposes. It may be true that some vapers experience lung problems, but whether these can be attributed to vaping is doubtful. Adverse events do occur across the population, and some will afflict people who vape, but not necessarily because of their vaping – this is common in adverse event reporting for medicines. It is also possible that adverse events would arise from prior or ongoing smoking. Even if there were adverse respiratory events caused by vaping, and this is far from established, they would be exceedingly rare – like severe allergic reactions to commonplace foods or substances. They do not form a reliable basis for regulation, especially the proposed flavour ban.

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<sup>1</sup> Blount BC, Karwowski MP, Shields PG, et al. Vitamin E Acetate in Bronchoalveolar-Lavage Fluid Associated with EVALI. *N Engl J Med* [Internet] 2020 [cited 2020 Dec 3];382(8):697–705. [[link](#)]

<sup>2</sup> Centers for Disease Control and Prevention (CDC). Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products. 2020 ; [[link](#)]

<sup>3</sup> Trimbos Institute. Factsheet Elektronische Sigaretten (E-sigaretten) April 2020 [[link](#)] See Reference 11. Translation [[link](#)]

<sup>4</sup> Geels M. Pulmonologists want a total ban on e-cigarettes in the Netherlands. NRC [Internet]. 2019; [[link](#)].