

Evidence review of nicotine vaping. Recommendations for regulation in Australia.

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Evidence review of nicotine vaping

Smoking is the leading preventable cause of death in Australia and our country is facing a significant challenge in reducing smoking rates. Vaping nicotine has emerged as a potential harm-reduction tool but misinformation hinders its acceptance. This document presents an overview of the evidence for vaping as a tool for smoking cessation and improving public health. It consists of 3 parts: 1) Key evidence 2) Common myths 3) Regulation.

Executive summary

Health effects

- Vaping is far less harmful than smoking
- Vapour contains only a small fraction of the chemicals in tobacco smoke and in much lower doses
- It is highly likely that the long-term risks of vaping will be considerably less than those of smoking
- There is currently no evidence that vaping is harmful to bystanders

Potential as a quitting aid

- Vaping is at least as effective as any other quitting method
- Vaping is the most popular method for quitting smoking in Australia
- As a result of its effectiveness and popularity, vaping is contributing to the accelerated decline in smoking in many countries where it is readily available

Youth vaping

- Most vaping by young never-smokers is experimental and short-term. Regular vaping is uncommon
- Youth vaping carries relatively minor health risks
- The association between vaping and smoking is most likely due to shared vulnerability
- The net effect of youth vaping at a population level is to displace smoking

Nicotine and dependence

- The evidence to date suggests vaping is less dependence-forming than smoking
- Nicotine is a relatively benign drug in the doses used in vaping

The current regulatory model has failed

- Australia's prescription-only regulatory model of vaping has produced a thriving black market controlled by criminal networks in which unregulated vaping products are sold freely to youth

Our conclusion

- Vaping is a safer alternative for adult smokers who are otherwise unable to quit smoking
- The current regulatory model is failing to prevent youth vaping

Based on the above we believe the best way forward is:

- Low concentrations of nicotine should be classified as a consumer product
- A tightly regulated consumer model with nicotine vapes sold as adult-only products by licensed retail outlets with strict age verification
- Harsh penalties and loss of licence for underage sales
- Regulations that are proportionate to risk and reflect the lower harms of vaping compared to smoking
- A parallel therapeutic goods route for products that meet TGA standards

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Key evidence

What is vaping?

Nicotine vapes (e-cigarettes) heat a liquid nicotine solution to create an aerosol, which can be exhaled as a visible mist or remain invisible when retained longer.

Vaping is a less harmful alternative for smokers who are unable to quit smoking with other methods. Vaping delivers the nicotine smokers are dependent on, with the hand-to-mouth action, habit, sensations, and social aspects of smoking.

Vaping is an effective quitting aid. It is used by smokers as a short-term quitting aid or for longer periods to prevent relapse to smoking (tobacco harm reduction). Some users continue to vape for the benefits of nicotine.

Devices. There are essentially three different types of vaping device (Figure 1).




 <p>Disposables Sealed, pre-filled single-use devices. Disposables are easy to use and do not require refilling or charging.</p>	 <p>Pod systems Comprise a rechargeable battery and a replaceable closed (sealed) or open (refillable) pod of e-liquid.</p>	 <p>Open systems Larger devices that comprise a rechargeable battery and a tank with a replaceable heating coil that can be refilled from a bottle of e-liquid. Open systems are more powerful and have adjustable settings.</p>
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Figure 1. Types of vaping devices

Nicotine. There are two types of nicotine used for vaping: free base and nicotine salt. Nicotine salt is less aversive on the throat and thus can be used at higher concentrations (2-6%). This enables devices that use them to be smaller and use less powerful batteries, such as disposables and smaller pod systems. Larger devices more commonly use the free base form (0.3-2%).

Vaping is far less harmful than smoking

Vaping is not risk-free, but it is beyond reasonable doubt that it is far less harmful than smoking. [1-5]

Almost all the harm from smoking is caused by the 7,000 chemicals in smoke (including 70 cancer-causing agents) that are released by burning tobacco. [6]

In contrast, vapes heat a liquid into an aerosol without combustion, tobacco or smoke. The aerosol typically contains around 100-150 chemicals [7, 8], mostly at low or trace levels compared to cigarette smoke. [9-11]

The far lower dose of potentially toxic chemicals is likely to cause far less harm, based on the toxicological principle that “the dose that makes the poison”. [12]

The UK [Royal College of Physicians](#) [3] and England’s [Office for Health Improvement and Disparities](#) [1] have both independently estimated that vaping is at least **95% less harmful** than smoking, based on comprehensive reviews of the science. This is not meant to be a precise figure but is to communicate the large difference in relative risk to smokers. This is based on:

Toxins As there is no combustion, almost all the toxic chemicals in smoke are absent from vapour. Those that are present occur in far lower doses than in tobacco smoke.

“Vaping poses only a small fraction of the risks of smoking” and is “at least 95% less harmful” than smoking
[England’s Office for Health Improvement and Disparities, 2022](#)

Toxins in the body	There are substantial reductions in toxins in the body fluids of smokers who switch to vaping. [13-15]
Health improvements	Studies of smokers who completely switched to vaping have shown improvements in asthma [16], chronic obstructive pulmonary disease (COPD) [17], blood pressure [18], muco-ciliary clearance [19], respiratory infections [20], lung function [21], respiratory symptoms [22, 23], cardiovascular markers [24, 25] and gum disease [26].
Cancer	The life-time cancer risk from vaping is estimated to be < 0.5% that of smoking. [27]
Mortality	There are no documented deaths from vaping nicotine but 8 million people die from cigarette smoking every year. Any serious side effects of vaping are very rare.

Long-term use is highly likely to be far less harmful than smoking

The precise long-term health effects of vaping will not be known for decades. However, based on the number and levels of toxins present, it is highly likely that it will be considerably less harmful than tobacco smoking.

Smokers who quit before the age of 35 years (typically within 20 years of starting smoking) have a normal life expectancy and are very unlikely to have long-term health effects. [28] It is therefore implausible that vaping for this duration would cause significant harms and that any harms would likely take far longer to develop.

“Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure”

UK [Royal College of Physicians](#), 2016

In the absence of long-term data, modelling studies are a well-accepted way of estimating the impact of an intervention. Numerous modelling studies estimate that wider use of vaping nicotine will have a significant net public health benefit [29-32] even if vaping generated 20% of the harm of smoking, a level that is very unlikely. [32]

The harms from long-term vaping are most probably considerably lower than for alcohol and most other drugs. No serious health effects are emerging in never-smoking vapers, although many have now vaped for several years.

As with any new product, it is possible that some harms may emerge over time so post-market surveillance should continue to monitor safety and detect any adverse effects.

There is now “high certainty” evidence that vaping nicotine is an effective quitting aid

Cochrane reviews (of randomised controlled trials) are the gold standard for determining whether a treatment works. The most recent [Cochrane review](#) of 6 studies concluded that vaping nicotine was 63% more effective for quitting than nicotine patches and gum. [33]

Two other high-quality reviews compared studies of vaping with all other quitting methods and concluded that vaping is among the most effective quitting aids:

- A review of 363 studies by the UK [National Institute for Health Research](#) found that vaping was the most effective single quitting aid. [34]
- Another [Cochrane review](#) in 2023 concluded that nicotine vapes and varenicline (Champix) were the two most effective treatments for quitting smoking. [35]

Vaping is more effective in helping smokers to quit than nicotine replacement therapy and is at least as effective as the most effective non-nicotine product (varenicline)

UK [National Institute for Health Research](#), 2021

Vaping is associated with increased quitting in observational studies [36-38], population studies [39-41], national smoking rates [42-44] and in the England Stop Smoking Service [1]). Vaping is also the only quitting aid to assist smokers with no intention of quitting (‘accidental quitters’). [45-47]

Combining different types of research with different strengths and weaknesses provides more conclusive evidence that vaping is an effective quitting aid.

The effectiveness of vaping is enhanced because smokers are willing to continue vaping for a more extended period compared to the use of alternative cessation products. Quit rates gradually increase over time. [36]

The impact of vaping on national smoking rates

Vaping is the most popular quitting aid in countries where it is readily and legally available, such as the UK, New Zealand and the UK. Because of its widespread use and effectiveness, vaping is replacing smoking at a population level.

Smoking rates in Australia have stagnated recently while falling rapidly in countries where vaping is more readily and legally available

Over the last 4 years, the prevalence of smoking has fallen rapidly in countries where vaping is readily accessible: 39% in New Zealand [43], 33% in Great Britain [42] and 18% in the United States [44]. (Figure 2)

By contrast, over the same period, the adult smoking rate in Australia declined by only 5% [48], even though Australian tobacco control policies are at least as strong. This suggests that discouraging vaping may be slowing progress in eliminating smoking in Australia.

In New Zealand, the adult smoking rate fell by an unprecedented 33% from 2020-2022 after the New Zealand Parliament legalised and regulated vaping in August 2020. [43] During the same two-year period, the smoking rate in Australia increased by 4.5%. [48]

Vaping is not the only cause for this rapid decline in smoking, but it appears to be making a significant contribution.

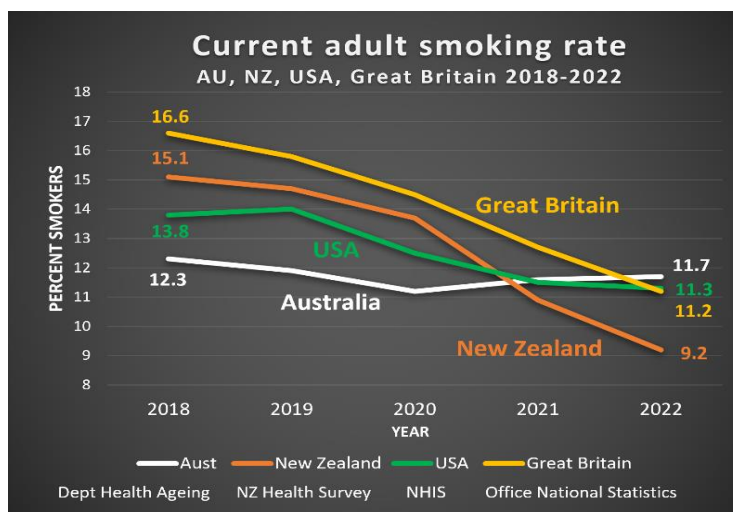


Figure 2. Smoking rates have flatlined in Australia while rapidly declining in NZ, the USA and GB

The challenge of youth vaping

Young people should not smoke or vape, but many will do so. Following is the key evidence on youth vaping:

Vaping may lead more young people to use nicotine

Young people who vape will include

- (1) Current or former smokers
- (2) Never-smokers who would have been smokers if vaping was not available, and
- (3) Non-smokers who would never have used nicotine in the absence of vaping.

There is legitimate concern about group (3). The level of concern should be proportionate to the number of young people in this group, how frequently they vape and the likely adverse effects of their vaping.

Australia's ban on the sale of consumer vapes has not prevented youth vaping.

Frequent vaping by non-smokers is rare

Most vaping by young people who have never smoked is experimental, occasional and short-term. Regular vaping is uncommon.

According to Australian research less than 2% of 14-17-year-olds who have never smoked vape nicotine **frequently**. [49, 50] (Figure 3) It is likely many of these would have been smokers if vaping was not available.

Measures of 'lifetime' vaping (vaping once or more) and 'vaping in the last 12 months' exaggerate the prevalence of regular use. Many young people vape only once or twice or occasionally. This is of little or no public health importance unless it translates later to regular and prolonged use.

Frequent vaping by current or former smokers is likely to be beneficial. [51-54]

Youth vaping carries relatively minor health risk

Most young non-smokers who vape do so infrequently and transiently. Only frequent vaping over the longer-term has the potential to cause harm, and serious harmful effects to date are very rare.

Some young people have reported cough or wheeze from vaping. [55, 56] However, there is no clear evidence that vaping causes "**functionally important**" respiratory symptoms. [57, 58] Youth vaping is not linked with the onset of asthma (although smoking is). [59, 60]

Vaping nicotine does **NOT** cause seizures [61] or pneumothorax (lung collapse). There is a very rare risk of burns from lithium-battery explosions, a risk from all devices that use these batteries, such as mobile phones and laptops.

Vaping diverts young people from smoking

Vaping and smoking are substitutes. Vaping is diverting some young people who would have otherwise smoked away from smoking. [62-64]

The increase in youth vaping has coincided with an accelerated decline in youth smoking in the UK [65], New Zealand [51] and the US [66, 67] (Figure 4). This is the opposite of what would be expected if vaping was a significant gateway to smoking.

Vaping may be a gateway to smoking for some young people, but this is outweighed by the much larger number who move from smoking to vaping. [68]

Some young smokers also switch from smoking to vaping, which is far safer.

No evidence that nicotine harms the human adolescent brain

High doses of nicotine can harm the brain in animal studies but there is no clear evidence of such harm in humans. [69] Cigarette smoking has not been found to impair IQ [70], educational achievement [71] or cognitive abilities [72] later in life, so it is very unlikely that vaping will do so.

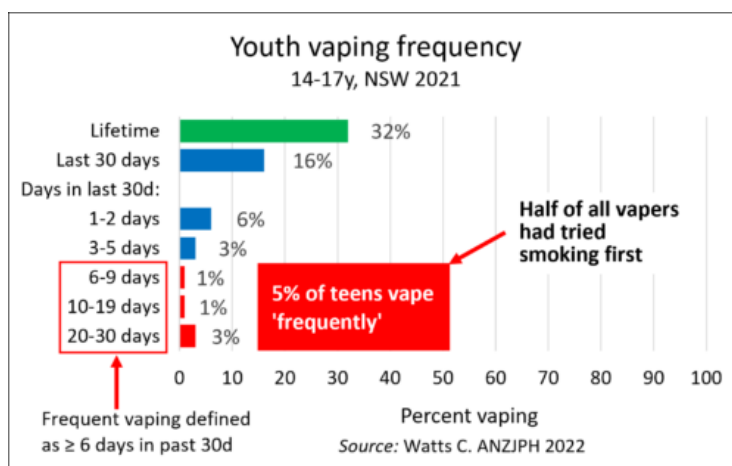


Figure 3. Frequent vaping by non-smoking youth is rare

"Most e-cigarette usage is infrequent and unlikely to increase a [young] person's risk of negative health consequences"

[R Polosa. J Allergy Clin Immunol Pract 2022](#)

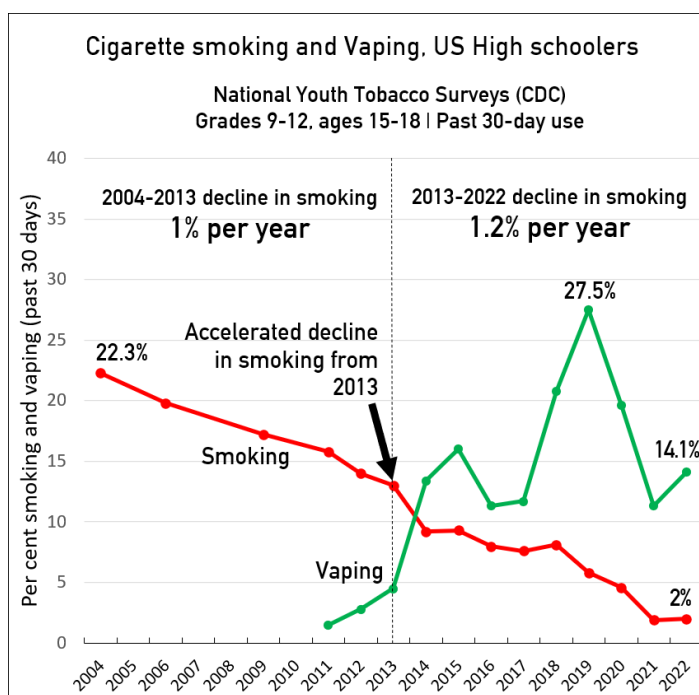


Figure 4. Accelerated decline in youth smoking in the US with increased youth vaping

Dependence in never-smokers is uncommon

Vaping can cause nicotine dependence in some young people who have never smoked. However, this is only in a small minority of cases. [73]

Nicotine dependence can lead to withdrawal causing short-term symptoms such as irritability, restlessness, anxiety, difficulty concentrating and depression. These symptoms are unpleasant but not serious.

Nicotine dependence is mostly concentrated in young people who are current or past smokers.

Reference for youth vaping: [Mendelsohn CP, Hall W. What are the harms of vaping in young people who have never smoked? International Journal of Drug Policy 2023](#)

Second-hand vapour is unlikely to cause any significant harms

Unlike second-hand tobacco smoke, there is no evidence that passive vaping is harmful to bystanders. [3, 4, 10]

Vaping releases extremely low levels of chemicals into the surrounding air. [74] Furthermore, the liquid droplets in vapour evaporate and disperse in seconds, much more quickly than the solid particles in smoke. [75]

“There is no evidence so far that vaping is harmful to people around you”

UK National Health Service, 2023

The lifetime lung cancer risk from second-hand vaping is estimated at 50,000 times less than passive smoking. [76]

Regulation of vaping

Current regulations in Australia

In Australia, nicotine vaping products are classified as unapproved prescription-only (S4) medicines, regulated by the Therapeutic Goods Administration. [77]

- Nicotine vapes can only be legally purchased with a doctor's prescription from a pharmacy or imported with a prescription from overseas under the TGA Personal Importation Scheme [78]
- It is an offence to sell nicotine vapes in Australia other than from a pharmacy
- Possessing nicotine e-liquid without a prescription is a criminal offence punishable by fines up to \$45,000 and/or 2 years jail [79]

Additional restrictions have been recently proposed and include [80]:

- Banning overseas importation
- A ban on disposable vapes
- A ban on flavours
- A maximum nicotine concentration of 20 mg/mL (2%)
- Pharmaceutical-like packaging
- More comprehensive standards for quality and safety for liquids and devices
- Improvements in labelling and enhanced compliance and enforcement measures.

Why the current regulations have failed

Australia's prescription-only regulatory model has had serious unintended negative consequences. It is acting as a barrier for smokers wishing to legally access vaping products. Less than 1% of doctors are publicly listed as nicotine prescribers [81] and only 8% of Australia's 1.3 million vapers have a prescription for nicotine. [82] Ninety two percent of vaping supplies are purchased through illegal channels.

The demand for vaping products has created a large black market controlled by criminal networks. [83] An estimated 90 million vapes are illegally imported from China each year and distributed through retail outlets and social media. [84] There is growing evidence of gang turf wars, retail shop intimidation, fire-bombings and gang-related murders. [85, 86] Money raised from tobacco sales is laundered and used to fund other criminal activities. [87]

Most of the demand comes from adults. The illicit and unregulated status of the products is likely discouraging use by smokers and reducing quitting. [88]

The black market also provides easy access to unregulated, mislabelled, high nicotine products to young people, causing considerable concern for parents and schools. [89]

Recommended regulatory approach

Regulation should strike a balance between making high quality nicotine vaping products readily available to help addicted adult smokers quit while also reducing access and appeal to young people. The preferred approach is:

- A tightly regulated consumer model in which nicotine vapes are sold as adult consumer products by licensed retail outlets, much like cigarettes and alcohol. [90] Vapes should be available from a wide range of outlets, so they are at least as accessible as combustible cigarettes.
- Strict age verification at the time of purchase, with harsh penalties for breaches and loss of retail licences.
- Regulations proportionate to risk and reflecting the lower harms of vaping relative to smoking. [91]

This would bring Australia into line with other western countries.

Under this model, the black-market would become less profitable and illicit sales would diminish over time.

This model was preferred by a majority of Australian adults in recent market research studies. [82, 92]

Consumer product classification

Low concentrations of nicotine liquid should be classified as a consumer product like cigarettes and should be removed from the Poisons Standard. This can be done at the state and territory or federal level. Nicotine e-liquids should be regulated by the Australian Competition and Consumer Commission.

Low concentrations of nicotine liquid should be removed from the Poisons Standard and classified as a consumer product

Disposables

A ban on single-use vapes has been proposed to reduce youth vaping. However, the disposables used by teens are already banned black market devices and a further ban is unlikely to have any effect on long-term supply and use. As vaping is diverting youth away from smoking, a disposable ban may also increase smoking. [62-64]

Disposable vapes are also a popular transition device for adult smokers, especially those with severe mental illness, homelessness, learning disabilities, hospital inpatients and older smokers who struggle with more complex vaping devices. A ban would remove an effective and popular quitting aid for vulnerable populations from the legal market. Restricting the sale of disposables to adult-only stores would reduce youth access without preventing access by smokers.

Disposable users should be encouraged to transition to pod or open devices once quitting is firmly established to reduce the environmental impact.

Flavours

Flavours play an important role in the initiation of vaping for adult smokers [93] and are associated with more quit attempts and higher quit rates. [94, 95]

- Banning flavours makes vaping less attractive as a quitting aid and increases smoking in young people [96] and adults. [97]
- Flavour bans lead to increased illicit supplies and dangerous home mixing. [98]
- However, flavours with known harms [10] or with disproportionate appeal to youth should be banned.

Flavours are not the primary reason for youth experimentation with vaping. The main reasons are curiosity and peer pressure, followed by liking the flavours. [99-101]

Nicotine concentration

The proposed nicotine limit of 20mg/mL (2%) is too low to satisfy more dependent smokers. Higher nicotine concentrations are more effective for quitting [47, 102, 103] and a nicotine concentration of at least 50 mg/ml (5%) is needed to match a cigarette. [104-106] Higher nicotine levels are in fact safer [107] – when the nicotine concentration is too low, vapers compensate by more and larger puffs and inhale more chemicals. [108, 109]

Taxation

Taxation of vapes should be proportionate to risk. Higher prices reduce vaping but increase smoking in youth [110, 111], young adults [112] and adults [113, 114]. Taxation at the level of the GST would bring Australia into line with the UK and New Zealand.

Reducing appeal to young people

Strategies to reduce youth vaping include [115]

- Legal vaping products sold only from licensed retail outlets
- Strict age verification at the time of sale
- A third-party age verification service for online purchases and on delivery
- Advertising restricted and regulated to prevent marketing to adolescents
- Substantially increased fines and loss of licence for underage sales
- Banning flavour names, images and packaging which appeal to young people

- Education programs for young people should frame vaping as an adult quitting aid and provide accurate information about the absolute and relative risks of vaping and smoking
- A proportionally higher taxation on disposable devices may reduce the affordability of these products for young people. However, the vast majority are sold on the black market and are not currently taxed.

Reference for regulation: [Mendelsohn CP, Wodak A, Hall W. How should nicotine vaping be regulated in Australia? Drug and Alcohol Review. April 2023](#)

Common myths about vaping

Myth 1. Vaping is a gateway to smoking

Young people who try vaping are more likely to later try smoking. [116] It was previously thought that vaping may have **caused** young people to take up smoking (“the gateway theory”).

FACT. A more likely explanation is that young people who engage in one form of risky behaviour, such as vaping, are more likely to engage in other risky behaviours such as smoking, hazardous alcohol consumption and illicit drug use (“common liability” hypothesis). [117]

“There may be a gateway effect for some young people, but it is outweighed by the much larger number moving from smoking to vaping”

[Mendelsohn C. Addiction 2023](#)

The preponderance of evidence is that vaping is not a gateway to smoking:

Population trends	The gateway theory predicts that vaping will increase smoking rates in young people. However, the opposite has occurred. Increases in youth vaping in the UK, US and New Zealand have been accompanied by accelerated declines in youth smoking rates. [51, 65, 67]
Restrictions on vaping increase smoking	Smoking and vaping are substitutes. Reducing access to vaping increases smoking, e.g., vaping bans [118]; increasing vape prices [110, 119, 120]; and age of sale restrictions. [121-124]
Vaping first (before smoking) reduces smoking uptake	Teens who vape first (before smoking) are less likely to smoke later, compared to those who smoke first. [125-127] There is no evidence that vaping first increases smoking uptake. [128, 129]

Myth 2. Nicotine is a dangerous poison

Because of its association with smoking, many people incorrectly believe nicotine is the harmful ingredient in tobacco smoke.

FACT. Nicotine in high concentrations is a dangerous poison. Although nicotine causes dependence it is a relatively benign drug in the low concentrations (0.3-6%) used in vaping. [3, 4, 130]

“Although nicotine is addictive, it is relatively harmless to health”

UK [National Health Service](#), 2023

Drinking large quantities of vaping liquid could be harmful, so nicotine liquid containers should have child-proof lids. The use of highly concentrated nicotine liquid (10-20%) requiring dilution for vaping, is largely due to attempts to circumvent the legal constraints on use.

Nicotine does not cause cancer [131] or lung disease [132] and only has a minor role in cardiovascular health. [133]

Myth 3. Vaping is a Big Tobacco conspiracy to addict a new generation

FACT. The tobacco industry did not invent vaping and currently only controls around 12% of the global vapour market. [134]

Concerns about the tobacco industry’s agenda are understandable because of its appalling past behaviour. However, the reality is that vaping is a huge disruptive threat to the tobacco industry because it directly competes with tobacco sales. The tobacco industry only began investing in vaping companies in 2012 in response to the clear threat and it has been trying to catch up ever since.

The tobacco industry is more interested in the heated tobacco product market where they have a natural marketing advantage, and the costs of entry are far higher than for vaping.

None of the disposable vapes sold in Australia on the black market and used by young people are made by tobacco companies. All are imported illegally, most directly from China.

Myth 4. Vaping causes “popcorn lung”

‘Popcorn lung’ (bronchiolitis obliterans) is a serious, but rare lung disease first detected in popcorn factory workers. It was linked to very high levels of ‘diacetyl’ which is used to create a buttery flavour.

FACT. There has never been a case of this condition reported from using nicotine vapes [135, 136] nor from cigarette smoking, which delivers diacetyl levels

hundreds of times higher than nicotine vapour. [137, 138] Diacetyl is now banned in Australia in e-liquids.

“E-cigarettes don’t cause the lung condition known as popcorn lung. There have been no confirmed cases of popcorn lung reported in people who use e-cigarettes”

[Cancer Research UK, 2023](#)

Myth 5. Most vapers smoke as well (dual use)

FACT. About one in two current vapers also currently smoke cigarettes (dual use). This is often a temporary transition phase as smokers adjust to vaping and many progress to quitting both vaping and smoking.

In Great Britain and in the United States, 37% of current vapers also smoke. [139, 140] In Australia, 54% of vapers also smoke. [99] Dual use tends to decrease over time as more quit smoking. [99] Experimental use of vaping while smoking was common when vaping was introduced, but experimental use has now declined.

Most dual users reduce their cigarette intake and so are exposed to lower toxin levels. [13] Studies show improvements in blood pressure [18] and asthma [141]. However, if dual users do not reduce their cigarette intake, then toxin levels are not reduced. [142]

Myth 6. Vaping is more addictive than smoking

FACT. Numerous studies have found dependence is significantly less from vaping than from smoking. [143-147]

This research is focused on adults who were almost all ex-smokers, but we think it likely to apply to youth and non-smoking adults.

Smoking is particularly addictive because it delivers high levels of nicotine very rapidly to the brain, more rapidly than vaping.

Smoke also contains other chemicals that make nicotine more addictive e.g., monoamine oxidase inhibitors. [148] These chemicals are not present in vapour.

There is emerging evidence that the uptake of vaping may have been faster than for smoking, likely in part due to it being less initially aversive, easier to use, and that it can be used more discretely (so in more places). However, there is no evidence that this translates into increased addiction.

“the risk and severity of [nicotine dependence] is lower than for cigarette smoking”

[England’s Office for Health Improvement and Disparities, 2022](#)

Myth 7. Vaping nicotine causes the serious lung injury, EVALI

In 2019 there was outbreak in the US of a serious and sometimes fatal lung injury in people who had recently vaped. It was mislabelled E-cigarette or Vaping Associated Lung Injury (EVALI). [149] EVALI has since been strongly linked with Vitamin E Acetate (VEA), a contaminant that was added to black-market cannabis oils, purchased from street dealers. [150]

FACT. Not a single case of EVALI has been linked to commercial cases nicotine vapes. When VEA was removed from the illicit supply chain, EVALI disappeared in early 2020. No further cases have been reported in the US [150] despite the continuing widespread use of nicotine vaping and no significant e-cigarette product changes.

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