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Hon Aaron Stonehouse MLC Chairperson Select Committee on Personal Choice and Community Safety Parliament House, 4 Harvest Terrace West Perth, WA, 6005

Dear Mr Stonehouse,

Thank you for the opportunity to make a submission and appear before the *Select Committee on Personal Choice and Community Safety*. Please find following our response to the questions we took on notice during our session on the 27 February 2019.

1. Are there currently any restrictions in the UK or US on how tobacco products can be advertised?

#### **United States:**

On June 22, 2009, President Barack Obama signed into law the Family Smoking Prevention and Tobacco Control Act, giving the U.S. Food and Drug Administration (FDA) comprehensive authority to regulate the manufacturing, marketing, and sale of tobacco products. The Family Smoking Prevention and Tobacco Control Act requires a number of restrictions on cigarette and smokeless tobacco product advertising and other marketing, and also grants the FDA authority to impose additional restrictions on the advertising, promotion and other marketing of tobacco products in order to promote overall public health. Newly effective with this act, "audio advertisements are not permitted to contain any music or sound effects, while video advertisements are limited to static black text on a white background. Any audio soundtrack accompanying a video advertisement is limited to words only, with no music or sound effects." The Family Smoking Prevention and Tobacco Control Act can be found here.

#### The Tobacco Control Act:2

a) Restricts Tobacco Marketing and Sales to Youth

These provisions ban:

- sales to minors
- vending machine sales (except in adult-only facilities)
- the sale of packages of fewer than 20 cigarettes
- tobacco-brand sponsorships of sports and entertainment events or other social or cultural events
- free giveaways of sample cigarettes and brand-name non-tobacco promotional items

## b) Requires Smokeless Tobacco Product Warning Labels

The Tobacco Control Act requires that smokeless tobacco packages and advertisements have larger and more visible warnings. Smokeless tobacco includes tobacco products such as moist snuff, chewing tobacco, and snus. Every smokeless tobacco package and advertisement will include one of the following warning label statements:

**WARNING**: This product can cause mouth cancer.

**WARNING**: This product can cause gum disease and tooth loss. **WARNING**: This product is not a safe alternative to cigarettes.

**WARNING**: Smokeless tobacco is addictive.

For smokeless tobacco packaging, the warning label statement must be located on the two principal sides of the package and cover at least 30% of each side. For advertisements, the warning label statements must cover at least 20% of the area of the ad. These changes aim to increase awareness of the health risks associated with smokeless tobacco use and improve the public health.

## c) Ensures "Modified Risk" Claims are Supported by Scientific Evidence

The landmark law prohibits tobacco companies from making reduced harm claims like "light," "low," or "mild," without filing an application for a modified risk tobacco product and obtaining an order to market as such.

## d) Requires Disclosure of Ingredients in Tobacco Products

Tobacco companies must provide the FDA with detailed information about the ingredients in their products.

Please refer to the latest Federal Trade Commission <u>Cigarette</u> and <u>Smokeless Tobacco</u> Report 2017 for the amounts spent on cigarette and smokeless tobacco advertising and promotion for the years 1970 through 2017. These tables list the amounts spent on the different types of media advertising (e.g., magazines) and sales promotion activities (e.g., distribution of coupons) and also give the percentage of the total amount spent for each of the various types of advertising and promotion.

## **United Kingdom:**

The United Kingdom (UK) is a Party to the World Health Organization's Framework Convention on Tobacco Control<sup>3</sup> (FCTC), the world's first global public health treaty. Article 13 of the Treaty requires Parties to implement and enforce a comprehensive ban on tobacco advertising within five years of ratifying the FCTC. Virtually all tobacco advertising is now illegal in the UK:<sup>4</sup>

- Tobacco advertising on television and radio was first prohibited by the Broadcasting Acts of 1990 and 1996, and the European Union's Audio-visual Media Services Directive.
- The Tobacco Advertising & Promotion Act 2002 (TAPA) was enacted in November 2002, which banned print media and billboard tobacco advertising in February 2003, tobacco direct marketing in May 2003, sponsorship within the UK in July 2003, with a gradual phase out of sponsorship of global events (such as Formula One motor racing) by July 2005.
- In 2004, space limitations were placed on the amount of advertising allowed at Point of Sale (with maximum allowance of 21x15cm). Since 2012 it has been illegal in England, Wales and Northern Ireland (and 2013 in Scotland) to display tobacco products in large stores, which was extended to small stores across the UK in April 2015.
- As part of the Health Act 2009, the sale of tobacco from vending machines became illegal in England since October 2011.
- With all these advertising bans in place, the tobacco pack became one of the few remaining
  promotional vehicles to reach potential and current tobacco users. In May 2016, Plain Packaging
  legislation came into force in the UK, requiring the removal of all branding on tobacco packs. Similar
  legislation was first introduced in 2012 in Australia, followed by Ireland.
- 2. Are there currently any restrictions in the UK or US on how vaping products can be advertised?

# **Unites States:**

In 2016, the FDA finalised a rule<sup>5</sup> extending the Centre for Tobacco Products (CTP) regulatory authority to cover all tobacco products, including electronic nicotine delivery systems (ENDS) that meet the definition of a tobacco product. It requires health warnings on roll-your-own tobacco, cigarette tobacco, and certain newly regulated tobacco products and also bans free samples. The deeming rule also requires that advertisements, including billboards, for all covered tobacco products bear an addictiveness warning statement. Effective

August 10, 2018, the tobacco product advertisement must bear the following required warning label statement: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." In addition, because of the rule, manufacturers of newly regulated tobacco products that were not on the market as of February 15, 2007, will have to show that products meet the applicable public health standard set by the law. And those manufacturers will have to receive marketing authorisation from the FDA. The new rule also restricts youth access to newly regulated tobacco products by:

- a) not allowing products to be sold to those younger than 18 and requiring age verification via photo ID
- b) not allowing tobacco products to be sold in vending machines (unless in an adult-only facility)

The FDA regulates the manufacture, import, packaging, labelling, advertising, promotion, sale, and distribution of ENDS, including components and parts of ENDS but excluding accessories. However, products marketed for therapeutic purposes (for example, marketed as a product to help people quit smoking) are regulated by the FDA through the Center for Drug Evaluation and Research (CDER). The FDA published a <u>rule clarifying</u> the jurisdiction over tobacco products, drugs, and devices.

# Manufacturing Electronic Nicotine Delivery Systems and E-Liquids

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import ENDS, you must comply with the requirements for manufacturers.

### Required Nicotine Addictiveness Warning on Packages and Advertisements

Beginning in 2018, all "covered<sup>1</sup>" tobacco products must bear the <u>required nicotine addictiveness warning</u> statement on product packages and advertisements.

### Retail Sales of Electronic Nicotine Delivery Systems and, E-Liquids

If you sell ENDS, e-liquids, or their components or parts made or derived from tobacco, the following <u>summary of federal rules for retailers must be followed</u>. You may also <u>order flyers</u> with rules for electronic nicotine delivery system sales or download a PDF to print yourself. You can find a list of retailer responsibilities for ENDS in the final rule <u>Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act.</u> In addition, their website offers more information on <u>regulations</u>, <u>guidance</u>, <u>and webinars for retailers</u>.

#### **Vape Shops That Mix E-Liquids or Modify Products**

If you operate a vape shop that mixes or prepares liquid nicotine or nicotine-containing e-liquids, or creates or modifies any type of ENDS, you may be considered a manufacturer. As a result, some vape shops may have legal <u>responsibilities as both manufacturers and retailers</u> of tobacco products. Please also see the <u>Draft Guidance</u>: Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops.

## Importing Electronic Nicotine Delivery Systems and E-Liquids

Tobacco products <u>imported or offered for import</u> into the United States must comply with all the applicable requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act). You can also learn more about the importation process in the FDA Regulatory Procedures Manual, Chapter 9, Import Operations and Actions.

<sup>&</sup>lt;sup>1</sup> Covered tobacco product means any tobacco product deemed to be subject to the FD&C Act under § 1100.2 of this chapter (i.e., subchapter K), but excludes any component or part that is not made or derived from tobacco (parts 1140, 1143).

## **United Kingdom:**

The EU Tobacco Products Directive,<sup>6</sup> which came into force in 2016, restricts the promotion and advertisement of e-cigarettes in all EU Member States. Under this e-cigarettes and refill containers cannot be directly or indirectly advertised or promoted:

- on TV or on-demand TV
- on radio
- through information society services (for example internet advertising and commercial e-mail)
- in certain printed publications (for example newspapers, magazines and periodicals)
- sponsorship of television and radio programmes which promotes e-cigarettes
- product placement of e-cigarettes
- sponsorship of activities or individuals that involve or take place in two or more European Economic Area (EEA) states or otherwise have cross border effects

The following however are permitted:

- blogs/tweets/independently compiled, non-paid for reviews
- e-cigarette trade press and trade to trade communication
- cinema, fax, outdoor posters, posters on sides of buses (not travelling outside of the UK), leaflets, and direct hard copy mail

In addition, advertising of e-cigarettes in media such as billboards and posters in shops is outside of the scope of the Directive. This means that national rules can be made. There are no current plans in England, Wales or Northern Ireland. However, the Health (Tobacco, Nicotine, etc. and Care) (Scotland) Act 2016 contains powers to make regulations to ban other kinds of advertising of e-cigarettes.

The restrictions on advertising within the implementing regulations will only apply to products that are covered by the Directive. Advertising will still be permitted, subject to the rules set out in the Committee of Advertising Practice (CAP) and BCAP codes (UK Code of Broadcast Advertising) for:

- non-nicotine liquids
- non-nicotine disposable e-cigarettes (not able to be refilled)
- non-disposable e-cigarettes designed to only take cartridges with non-nicotine containing fluid
- medicinal products (subject to separate medicines advertising legislation)

Such advertising must not indirectly promote nicotine containing products.

# 3. Can you please provide more information about the US study which cited that 20.8% of high school students are currently vaping?

The source of this claim is cited as: Cullen K, Ambrose B, Gentzke A, Apelberg B, Jamal A, King B. Notes from the field: Use of electronic cigarettes and any tobacco product among middle and high school students — United States, 2011–2018. Morbidity and Mortality Weekly Report (MMWR). 2018; 67:1276-7.

Data included in this report were data from the 2011–2018 National Youth Tobacco Survey (NYTS), a cross-sectional, voluntary, school-based, self-administered, pencil-and-paper survey of United States (U.S) middle and high school students. NYTS uses a three-stage cluster sampling procedure to generate a nationally representative sample of U.S. students attending public and private schools in grades 6–12. Briefly, primary sampling units are selected at the first stage, schools are selected at the second stage, and students are selected from intact classrooms at each grade level at the third stage. This report used data from seven NYTS waves (2011–2017). Sample sizes and response rates were 18,766, 72.7% (2011); 24,658, 73.6% (2012); 18,406, 67.8% (2013); 22,007, 73.3% (2014); 17,711, 63.4% (2015); 20,675, 71.6% (2016); and 17,872, 68.1% (2017).

The study is analysed to determine the prevalence of current use (≥1 day in past 30 days) of e-cigarettes,\* current use of any tobacco product, frequency of (number of days during the preceding 30 days) e-cigarette use, and current use (any time during preceding 30 days) of any flavoured e-cigarettes among U.S. middle school (grades 6–8) and high school (grades 9–12) students.<sup>8</sup>

\*Current e-cigarette use was defined as a response greater than "0 days" to the question, "During the past 30 days, on how many days did you use e-cigarettes?" The e-cigarette questions were preceded by the following information: "The next 11 questions are about electronic cigarettes or e-cigarettes. E-cigarettes are battery powered devices that usually contain a nicotine-based liquid that is vaporized and inhaled. You may know them as e-cigs, vape-pens, hookah-pens, e-hookahs, e-cigars, e-pipes, personal vaporizers, or mods. Some brand examples include NJOY, blu, Vuse, MarkTen, Logic, Vapin Plus, eGo, and Halo."

Data were weighted to account for the complex survey design and adjusted for nonresponse. National prevalence estimates with 95% confidence intervals and population estimates rounded down to the nearest 10,000 were computed. The presence of linear and quadratic trends during 2011–2017 were assessed, adjusting for race/ethnicity, sex, and grade.<sup>††</sup> T-tests were performed to examine differences between 2016 and 2017. For all analyses, p-values <0.05 were considered statistically significant.<sup>7</sup>

<sup>††</sup> A test for linear trend was significant if an overall statistically significant decrease or increase occurred during the study period. Data also were assessed for the presence of quadratic trends. A significant quadratic trend indicated that the rate of change accelerated or decelerated across the study period.

Results of the study,<sup>8</sup> in regards to e-cigarettes, which were reported state:

Among high school students, current e-cigarette use increased from 1.5% (220,000 students) in 2011 to 20.8% (3.05 million students) in 2018 (p<0.001) (Figure). During 2017–2018, current e-cigarette use increased by 78% (from 11.7% to 20.8%, p<0.001). The proportion of current e-cigarette users who reported use on  $\geq$ 20 of the past 30 days increased from 20.0% in 2017 to 27.7% in 2018 (p = 0.008). Among high school students, during 2017–2018, current use of any flavoured e-cigarettes increased among current e-cigarette users (from 60.9% to 67.8%, p = 0.02); current use of menthol- or mint-flavoured e-cigarettes increased among all current e-cigarette users (from 42.3% to 51.2%, p = 0.04) and current exclusive e-cigarette users (from 21.4% to 38.1%, p = 0.002).

Among middle school students, current e-cigarette use increased from 0.6% in 2011 (60,000 students) to 4.9% (570,000 students) in 2018 (p<0.001) (Figure). During 2017–2018, current e-cigarette use increased by 48% (from 3.3% to 4.9%, p = 0.001); the proportion of current e-cigarette users who reported use on ≥20 days of the past 30 days did not significantly change (from 12.9% to 16.2%, p = 0.26).

Current e-cigarette use increased considerably among U.S. middle and high school students during 2017–2018, reversing a decline observed in recent years and increasing overall tobacco product use. Moreover, during 2017–2018, frequent e-cigarette use increased among high school students.

The rise in e-cigarette use during 2017–2018 is likely because of the recent popularity of e-cigarettes shaped like a USB flash drive, such as JUUL; these products can be used discreetly, have a high nicotine content, and come in flavours that appeal to youth. In September 2018, the Food and Drug Administration (FDA) issued more than 1,300 warning letters and civil money penalty fines to retailers who illegally sold e-cigarette products to minors, the majority of which were blu, JUUL, Logic, MarkTen XL, and Vuse; this was the largest coordinated enforcement effort in FDA's history. Sustained implementation of proven population-based strategies, in coordination with the regulation of tobacco products by FDA, is key to reducing all forms of tobacco product use and initiation, including e-cigarettes, among U.S. youths.

Thank you for your time and this opportunity.

Yours sincerely,

KM Causland .

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