

# E-CIGARETTES

## POLICY ENVIRONMENT

The emergence of e-cigarettes and the resulting explosion of youth e-cigarette use have presented regulatory challenges. These issues include determining policies to deter youth use, appropriate taxation, clean air regulations, as well as standards for product approval. There is a web of policy approaches to these issues at all levels of government, including the federal, state, local and international level.

### FDA REGULATION

In May 2016, the FDA finalized its “deeming” regulation, asserting the agency’s authority to regulate e-cigarettes and any product meeting the definition of “tobacco product” under the Tobacco Control Act.<sup>1</sup> The **FDA can now establish product standards and regulate the manufacture, import, packaging, labeling, advertising, promotion, sale and distribution of e-cigarettes**, including components and parts of e-cigarettes.<sup>1</sup>

The deeming regulation includes requirements for pre-market review for e-cigarettes as new tobacco products. In order to receive marketing approval for a new product, a manufacturer must demonstrate that the marketing of the new product would be “appropriate for the protection of public health,” taking into account both the likelihood of new tobacco product initiation and the increased or decreased likelihood that existing users of current tobacco products would stop using those products.<sup>1</sup>

When FDA “deemed” e-cigarettes as part of its jurisdiction in 2016, it gave e-cigarettes that were currently on the market two years to prepare premarket applications (known as PMTAs).<sup>1</sup> These applications are what FDA uses to determine whether new tobacco products are “appropriate for the protection of public health” before they are allowed on the market.<sup>2</sup> In 2017, FDA extended the



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deadline for completed applications to August 2022.<sup>3</sup> When several public health groups, including Truth Initiative, sued FDA, a federal court ordered the agency to require applications be submitted by May 2020.<sup>4</sup> The deadline changed again to September 9, 2020, following FDA and tobacco industry requests for more time due to the COVID-19 pandemic.<sup>5</sup>

Now that the September 9, 2020 deadline has passed, FDA has begun reviewing thousands of applications to determine if those products meet the public health standard set by the Tobacco Control Act. While the agency is supposed to conduct its review of those products in one year, FDA’s Center for Tobacco Products director has admitted “the likelihood of FDA reviewing all of these applications during the one-year review period is low,”<sup>6</sup> foreshadowing yet more delays in necessary and urgent regulatory action.

## MODIFIED RISK TOBACCO PRODUCTS

- > Under FDA rules, before an e-cigarette manufacturer can market a product as presenting lower risk of exposure to toxins or lower risk of adverse health effects, it must submit the proposed marketing and labeling to the FDA so that it can assess veracity of the claim and whether the marketing of the product would benefit the health of individuals and the population as a whole, considering such factors as new initiation of tobacco use or suppression of cessation of more harmful products such as cigarettes. To date, no e-cigarette manufacturer has requested such permission from the FDA.



## Legal challenges to e-cigarettes

A series of **lawsuits** in recent years have also been brought **against JUUL and other e-cigarette manufacturers** by young people who became addicted to JUUL, claiming **JUUL's marketing was aimed at youth** and instigated these plaintiffs' use. California, North Carolina, Illinois, Connecticut, Colorado, Massachusetts and the District of Columbia have announced either litigation or investigation into JUUL's marketing practices and/or health claims.<sup>136-141</sup>

## CLEAN INDOOR AIR POLICIES

- > There are no federal policies restricting indoor use of e-cigarettes other than policies in individual federal buildings or properties.
- > 22 states and 970 municipalities have expanded their smoke-free air laws to also prohibit e-cigarette use in places where cigarette smoking is prohibited.<sup>7</sup>

## FLAVORS

- > The Tobacco Control Act bans characterizing flavors other than menthol from cigarettes. Non-cigarette products are not included, but the FDA does have power to issue such bans for other products, such as e-cigarettes, by developing product standards. The FDA has yet to take such action. However, the FDA issued an enforcement policy in January 2020 that effectively bans flavored cartridge-based e-cigarettes, other than menthol.<sup>8</sup> Therefore, under current federal law, most e-cigarette products, such as e-liquids and refillable tanks, disposable e-cigarettes and menthol flavored pod e-cigarette products are allowed on the market.
  - >> As FDA reviews e-cigarette products, it will be important to monitor whether any flavored products are authorized for sale. Truth Initiative has encouraged FDA not to authorize any flavored e-cigarettes other than tobacco flavor because they attract youth and harm public health.
- > As of December 31, 2020, seven states and an estimated 330 counties, cities, towns, and tribes have restricted the sale of flavored e-cigarettes.<sup>9</sup> However, a large majority of the U.S. population is not covered by such restrictions.
  - >> In 2019, **Massachusetts** became the first state to enact a comprehensive ban on the sale of all flavored tobacco products, except in smoking bars, such as cigar bars and hookah lounges, where it is allowed for on-site consumption.

- » **California** enacted a law to prohibit the sale of all flavored tobacco products, except hookah, premium cigars, and pipe tobacco. However, the tobacco industry successfully sought a referendum and the law will be voted on by the state's voters on the next statewide ballot, currently scheduled for November 2022, though this date is subject to change.
- » The **Maryland** Comptroller's Field Enforcement Division prohibits the sale of flavored cartridge-based e-cigarettes and disposable e-cigarettes, except for menthol.
- » **New Jersey** and **Rhode Island** prohibit the sale of all flavored e-cigarette products. Rhode Island's policy is a regulation by the state's health department, making permanent the governor's emergency regulations.
- » **New York** prohibits the sale of all flavored e-cigarettes, except those approved as part of an FDA premarket approval.
- » **Utah** restricts the sale of flavored e-cigarettes, except menthol and mint, to non-retail tobacco specialty businesses.

## MARKETING

- > There are **few federal restrictions on the marketing of e-cigarettes**, and, unlike traditional cigarettes, e-cigarettes can be advertised on television and radio.
- > **Marketing materials of e-cigarettes cannot make claims that their product exposes users to fewer toxins or reduces harm unless the FDA grants an order allowing such claims.**
- > **E-cigarette products whose labeling or advertising is misleading can be considered to be misbranded under the Tobacco Control Act.** This includes e-cigarette marketing that imitates food or beverages, as mentioned above.



Unlike traditional cigarettes, e-cigarettes can be advertised on television, radio, digital media and social media.

- > **States have the ability to regulate the time, place and manner of tobacco marketing, including e-cigarettes.**<sup>10,11</sup> For example, **Colorado** prohibits retailers from advertising e-cigarettes in a manner that is visible from outside the retail location, **Delaware** prohibits web sites and online and mobile applications directed at minors from marketing or advertising e-cigarettes, and **New York** prohibits advertisements for e-cigarettes from display in store fronts, exterior windows and doors of stores within 1,500 feet of a school (500 feet for New York City).<sup>12</sup>

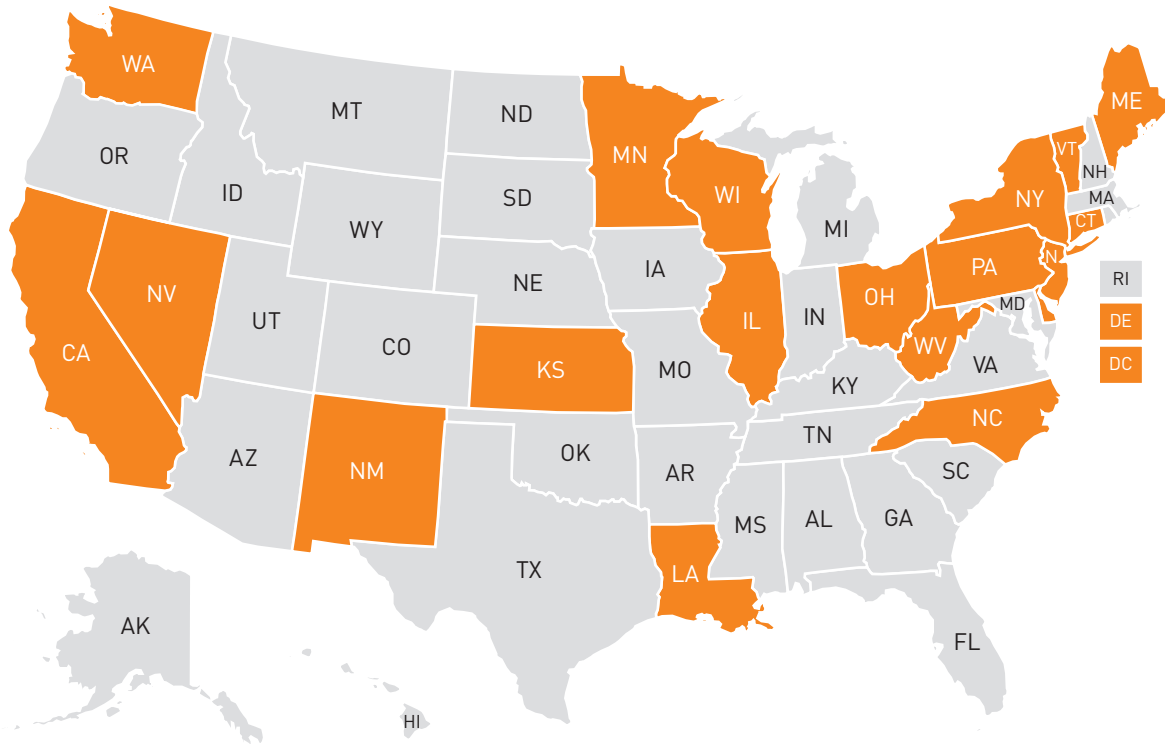
## PRODUCT PACKAGING

- > The FDA deeming regulation, effective Aug. 10, 2018, established a **nicotine warning label** that must appear on all tobacco products, including **e-cigarettes**:

**WARNING:** This product contains nicotine. Nicotine is an addictive chemical.<sup>3</sup>

The warning label must comprise 30% of the two principal display panels and be in a large, legible font.

Nineteen states and Washington, D.C., have imposed a **tax on e-cigarettes**.



- > **The Child Nicotine Poisoning Prevention Act of 2015 requires the Consumer Safety Product Commission to establish requirements for child-resistant packaging for e-cigarettes and e-liquids.** The law, passed before the deeming regulation gave the FDA authority over e-cigarettes, maintains the FDA's ability to regulate such packaging. The FDA has indicated that it will also issue regulations requiring child-resistant packaging for e-cigarettes and e-liquids, but has not yet done so.

## TAXATION

- > There is **no federal excise tax on e-cigarettes**.
- > States have the authority to tax e-cigarettes. **Nineteen states and the District of Columbia have imposed a tax on e-cigarettes.**<sup>12</sup>

## YOUTH ACCESS AND MINIMUM AGE OF SALE

- > In December 2019, the U.S. adopted a law **raising the federal minimum age of sale for all tobacco products to 21 years old**, effective immediately. Retailers must check photo IDs of everyone under age 27 who attempts to purchase tobacco products, including e-cigarettes.
- > **Vending machine sales of e-cigarettes are prohibited**, except in facilities where only those over 18 are allowed.
- > **Free samples of e-cigarettes and their components are also prohibited** as of Aug. 8, 2016.<sup>11</sup>
- > The Tobacco Control Act required the FDA to issue regulations to **establish age verification requirements for the internet and other non-face-to-face purchases of any tobacco products**. However, the FDA has yet to implement this set of regulations.



- > 30 states have **established a minimum age of 21 for the sale of tobacco products**.<sup>13</sup> States and some localities have the ability to establish a higher age of sale for tobacco products beyond the federal requirement.
- > In 2020, the U.S. Congress passed the **“Preventing Online Sales of E-cigarettes to Children Act”** which prevents the mailing of e-cigarettes through the mail, and other carrier services, similar to existing bans on mailing cigarettes and smokeless tobacco. Products approved by FDA as cessation products or for other therapeutic purposes are exempt from this provision (e.g. Nicotine Replacement Therapies such as nicotine gum, or patches).<sup>14</sup>

## INTERNATIONAL POLICIES

International regulation of e-cigarettes **varies widely**, and, due to the relatively recent introduction of the product category, is rapidly changing.

- > The Institute for Global Tobacco Control at the Johns Hopkins Bloomberg School of Public Health keeps a database of international e-cigarette laws.<sup>15</sup> 30 countries ban the sale of all types of e-cigarettes, 49 countries regulate the sale of e-cigarettes or require marketing authorization prior to sale, four countries prohibit the sale of nicotine-containing e-cigarettes, and six countries do not have regulations on the sale of e-cigarettes beyond age of majority purchase rules.<sup>15</sup>

- > The European Union has enacted standards for e-cigarettes, including restricting the strength of nicotine fluids (2 percent maximum), limiting tank size on vaping devices (2ml maximum), requiring child resistant packaging and prohibiting cross-border advertising of e-cigarettes.<sup>16</sup> Some member states have further restrictions on the age of sale and taxes.<sup>17</sup>
- > Notably, **the United Kingdom has been most active in promoting e-cigarettes as a reduced harm alternative to cigarettes**.<sup>18</sup> Public Health England has encouraged the National Health Service to make e-cigarettes available to smokers looking to quit or switch.<sup>18</sup> The UK allows for the licensing of e-cigarettes as medicinal quitting aids, but no manufacturer has yet taken this route to product approval.<sup>19</sup> In addition, the UK has stringent restrictions on the marketing of e-cigarettes.<sup>20</sup>

Unlike in the U.S., a significant portion of countries with e-cigarette policies prohibit or regulate e-cigarette marketing.



Photo: Stanford Research into the Impact of Tobacco Advertising

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