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Regulation of Electronic Cigarettes: A Review of Selected Key Regulations by the EU, the US Federal Government, and the State of California

Jose Perez

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Abstract

This paper reviews the regulatory actions of the EU, US federal and California governments concerning the regulation of electronic cigarettes.

Regulation concerning electronic cigarettes has been an area of focus in those jurisdictions since the beginning of the last decade. That focus has been driven, in part, by the fact that minors are particularly susceptive to purchasing electronic cigarettes. This is detrimental to their health for two main reasons. First, cigarettes contain nicotine, which has been demonstrated to cause addiction and deleterious effects on the health of young people. These effects include interference with normal brain development and cognition. Second, nicotine-addicted youth may eventually switch to, or concurrently smoke, traditional cigarettes. Decades-worth of research has shown that smoking tobacco-containing traditional cigarettes is even more harmful to the health than smoking nicotine-only products and is, in fact, one of the leading causes of major diseases and death in the EU and the US.

To address these concerns, the referenced governments have enacted complex regulations that have been organized into the following framework for analysis: (1) manufacturing regulations concerning the use of flavorings, (2) health warnings, (3) promotion regulations concerning health-based messaging and events sponsorships, (4) sale regulations concerning minimum age of purchase, self-service sales and distance sales, and (5) taxation concerning *ad valorem* and specific taxes. For each of those types of regulation, this paper first provides a general overview of what has been regulated and, as relevant, the scientific or other evidence-based rationale for enacting such regulations. Subsequently, the relevant regulations of each jurisdiction are analyzed in turn within the five categories of the framework. Finally, the regulatory actions of all governments are brought together to contextualize the appropriateness of their relative breadth of scope.

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List of Abbreviations

CA	State of California
CDC	Centers for Disease Control and Prevention
EU	European Union
FCTC	World Health Organization Framework Convention on Tobacco Control
FDA	United States Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
LAO	California Legislative Analyst's Office
NRT	Nicotine Replacement Therapy
POSECA	Preventing Online Sales of E-Cigarettes to Children Act
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
US	United States
WHO	World Health Organization

1. Introduction

This thesis considers and compares selected key regulations relating to the manufacturing, marketing, sale and taxation of electronic cigarettes in the EU, at the federal level in the US and in the State of California. An electronic cigarette is a device that heats liquid nicotine, producing a vapor that users inhale. It generally comprises a battery; a cartridge (containing liquids such as nicotine and flavorings); and an atomizer that heats the cartridge, vaporizing its contents. Some electronic cigarettes are reusable, allowing the consumer to replace a spent liquid cartridge; others are single-use, disposable devices. For purposes of this thesis, the term electronic cigarette refers to all such devices, and associated liquid cartridges, that contain nicotine.

To place the impetus of that regulatory action in the correct context, this thesis presents, as appropriate, research and other source material that was available and relevant at the time in which those regulations were first introduced. For example, on the eve of the original regulatory efforts, the results of analyses of cartridge samplings were finding potentially harmful substances in electronic cigarettes' chemical cocktails and vapor emissions.[1] In addition, electronic cigarettes contained unregulated levels of nicotine, which is an addictive and harmful substance.[2] Further, in addition to the deleterious health effects it

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[1] *See, e.g.*, Ben McPartland, *Report: E-cigarettes are "Potentially Carcinogenic"*, THE LOCAL, Aug. 26, 2013, http://www.thelocal.fr/20130826/e-cigarettes-are-potentially-carcinogenic.

[2] *See, e.g.*, Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products and Repealing Directive 2001/37/EC, 2014 O.J. (L 127/1) 1-38, recitals 41, 43 (concerning the addictiveness of nicotine) [hereinafter *Tobacco Products Directive*].; U.S. SURGEON GENERAL, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL (2016), 99, https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

may cause directly, nicotine addiction may also lead users to smoke traditional tobacco products,[3] which poses an undebatable even more significant risk to public health.

Importantly, operating in the background of the governmental interest in regulating electronic cigarettes was the fact that children under 18 years old were a growing segment of electronic cigarette users. Based on the results of the National Youth Tobacco Survey ("**US Tobacco Survey**") conducted by the US Centers for Disease Control and Prevention ("**CDC**") in 2011 and 2012, the US smoking rate of electronic cigarettes among students in grades 6 through 12 grew steadily between 2011 and 2015.[4] In some instances, the growth rate resulting in almost double the number of youth users comparing one year to the next. In the EU, a key motivator for developments in the area of regulating tobacco and tobacco-related products was also preventing European youth from developing a smoking habit.[5] And the rates of use of electronic cigarettes were also increasing.[6]

In connection with a draft directive for the regulation of tobacco products, including electronic cigarettes, being overwhelmingly passed by the EU Parliament in October 2013, the Parliament Press Office published a press release emphasizing that smoking was the leading cause of preventable death in the EU, causing 700,000 deaths a year.[7] In addition,

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[3] *E.g.*, Tobacco Products Directive recital 43.
[4] Tushar Singh e al., *Tobacco Use Among Middle and High School Students — United States, 2011–2015*, MMWR and Morbidity and Mortality Weekly Report (Apr. 15, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm6514a1.htm.
[5] *See* Press Service, Directorate for the Media, European Parliament, Tobacco Directive: Preventing the Young from Picking up a Deadly Habit (2013), [hereinafter Parliament Press Service, *EU Youth Smoking Prevention*] *available at* http://www.europarl.europa.eu/pdfs/news/public/story/20130719STO17437/20130719STO17437_en.pdf; This interest in protecting European Youth is clear on the face of the Tobacco Products Directive. *See, e.g.*, Tobacco Products Directive art. 1, recitals 19, 21, 26-27, 33, 47.
[6] Filippos T. Filippidis, et al., *Two-year Trends and Tredictors of E-cigarette Use in 27 European Union Member States*, TOBACCO CONTROL, May 2016, at 98-104, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5256312/.
[7] Parliament Press Service, *EU Youth Smoking Prevention*, *supra* note 5.

the press release indicated that of the 25% of Europeans who smoke, 94% are addicted before they turn 25 years old.[8] Notably, at that time, health data demonstrated that 18.5% of 15-year-olds in the EU smoked at least once a day.[9] Electronic cigarette regulation was relevant in light of those statistics because not only is the nicotine in such devices addictive, they also may, as noted above, be gateways that result in the youth's eventual transitioning to consuming traditional tobacco products when they reach adulthood.

In other words, research and statistics at the time revealed a two-fold issue. First, the American and European youth was increasingly using unregulated products that contained nicotine, which is a substance harmful to minors, and in some cases contained other harmful ingredients. Second, that harm might have been compounded by the fact that minors who became addicted to nicotine as a result of consuming electronic cigarettes could be at risk of transitioning to traditional tobacco products, which presented even more harmful health risks on an individual level and from a public health perspective.

Notwithstanding the foregoing, it must be acknowledged that the factors that influence the health effects of electronic cigarettes are more complex than bare statistics may suggest and include, for example:

- "(1) external factors (such as climate conditions, airflow, particulate size, number of users in the vicinity);
- (2) e-cigarette characteristics (such as type and age of the vaping instrument, battery voltage, puff length, interval between the puffs);

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[8] *Id.*

[9] Press Service, Directorate for the Media, European Parliament, The Deadly Habit: Public Health Committee Votes to Ban Slim and Flavoured Cigarettes (2013), [hereinafter Parliament Press Service, *Youth Smoking Habit*], https://www.europarl.europa.eu/news/en/headlines/society/20130708STO16805/public-health-committee-votes-to-ban-slim-and-flavoured-cigarettes.

- and (3) user characteristics (such as age, gender, experience, health status of users)"[10]

Evidently, such high variance of health risk factors and their complicated interrelationship make it difficult to pursue regulatory efforts. However, those complex circumstances justify the current regulatory approach when reduced to one of its most basic results: reducing the variance levels of those factors. In other words, the current regulatory efforts discussed in subsequent sections contribute to reducing the variance in:

- Electronic cigarette characteristics by establishing standards for the manufacture of electronic cigarettes, particularly regarding the amount and delivery of nicotine; and
- User characteristics by directly limiting the groups of consumers who have access to electronic cigarettes (such as through introducing minimum age to purchase them) or indirectly such as by making them more expensive, which is expected to disproportionately affect purchasing behavior of typically income-limited minors.

As those factors surrounding electronic cigarettes become more homogenous, studying their health impact should become easier and allow for more scientifically sound conclusions. This, in turn, would inform how governments should approach regulating electronic cigarettes in the future.

1.1. Introduction to EU Regulation of Electronic Cigarettes

In part in recognition that electronic cigarettes threaten the health of European youth, the EU enacted a directive aimed at regulating tobacco products, known as the Tobacco

[10] Sakshi Sapru at al., E-*cigarettes Use in the United States: Reasons for Use, Perceptions, and Effects on Health*, BMC PUBLIC HEALTH, Oct. 2020, at 5, https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-09572-x.

Products Directive, which contains provisions aimed at regulating electronic cigarettes in its Article 20.

However, it must be noted that intense industry lobbying[11] during the legislative process resulted in a relatively narrow scope of regulatory action for electronic cigarettes under the Tobacco Products Directive. Therefore, a discussion of the Tobacco Products Directive and its design would not be fulsome without first noting that as a draft of the Directive originally came into discussion, the EU Parliament tabled almost 1,500 amendments.[12] And that is no surprise: industry groups intensely lobbied EU Parliament members.[13] In fact, some members blamed a delayed October 2013 vote on the Directive (initially scheduled for September 2012) on lobbying efforts.[14] Others, such as the co-chair of the Public Health Committee, went further and pointed out that tabled amendments "align with a [Philip Morris] wish-list of five main legislative changes."[15] Namely, removing a menthol ban, placing health warnings at the bottom of a pack, easing restrictions on electronic cigarettes, and smaller warning labels.[16]

Separately, the EU has an online lobbyist database, but registration is voluntary, and, at the time the Directive was being drafted, generally left EU Parliament members free to meet lobbyists without public disclosure.[17] However, special rules applied to the tobacco industry: if politicians met with industry lobbyists, the meetings were required to be

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[11] *See, e.g.*, Jane Deith, Lobbyists Puff and Blow over New EU Tobacco Rules, BBC NEWS UK, July 16, 2013, http://www.bbc.co.uk/news/uk-23330553.
[12] *Id.*
[13] *See, e.g.*, *id.*; *see also MEPs tighten anti-tobacco laws aimed at young smokers*, BBC NEWS UK, October 8, 2013, http://www.bbc.co.uk/news/world-europe-24439474.
[14] Nikolaj Nielsen, *Tobacco Giant Spent Up to €1.25m on EU Lobbying in 2012*, EU OBSERVER, October 3, 2013, http://euobserver.com/institutional/121657.
[15] *Id.*
[16] *Id.*
[17] Deith, supra note 2. *Lobbyists Puff and* Blow, *supra* note 11.

transparent.[18] Still, some tobacco companies were creative in their efforts to influence legislators, according to parliament member Linda McAvan, who ushered the directive through Parliament.[19] For example, McAvan accused a tobacco company of calling her constituency office, "posing as a representative of small retailers to demand an urgent meeting."[20] Other manufacturers sent multiple anonymous amendments to members of parliament.[21]

According to a Corporate Europe Observatory report, members of the EU Parliament reported receiving free electronic cigarettes delivered by mail; office visits from tobacco lobbyists; numerous drinks, dinner and cocktails invitations; and "targeted social media and email campaigns coordinated by tobacco companies."[22] All in all, lobbying tactics to represent tobacco interests at the EU Parliament involved the spending of millions of Euros, with Phillip Morris International alone spending between €1 million and €1.25 million.[23]

As ultimately enacted, Article 20 of the Tobacco Products Directive reflects a mixed regulatory approach: one for electronic cigarettes that do not make any health claims, which are covered by the Tobacco Products Directive, and a different one for those that do, which are not covered.[24] In essence that means that electronic cigarettes presented as having curative or preventative properties are subject to the regulations applicable to medicinal products. That is an appropriate regulatory approach because manufacturers that

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[18] *Id.*
[19] *Id*.
[20] *Id*.
[21] *Id*.
[22] Lobbycracy, *Tobacco lobbyists all fired up ahead of key vote*, CORPORATE EUROPE OBSERVATORY, July 8, 2013, http://corporateeurope.org/lobbycracy/2013/07/tobacco-lobbyists-all-fired-ahead-key-vote.
[23] Nielsen, *supra* note 14.
[24] *See* Tobacco Products Directive art. 20(1).

voluntarily employ a health-based marketing strategy to sell their products should have to prove their claims and be subject to meeting stricter regulatory standards.

In addition, the regulatory approach in the Tobacco Products Directive resulted in the selective application to electronic cigarettes of only some provision that were applicable to traditional tobacco products,[25] as well as on the application to electronic cigarettes of some provisions that were not applicable to traditional tobacco products.[26] That disparate treatment of both types of products led to an unsuccessful challenge of the Tobacco Products Directive not long after it was enacted, which is discussed below.

A discussion of the provisions of Article 20 of the Tobacco Products Directive relevant to this thesis is set forth in subsequent sections. The final date for transposing those provisions, and indeed the Tobacco Products Directive in total, into national law was May 20, 2016. Therefore, the provisions of Article 20 of the Tobacco Products Directive, the validity of which have been upheld as discussed, should now be effective in all Member States.

1.1.1. Selected Legal Challenges Against the Tobacco Products Directive

In the case *Pillbox 38 (UK) Ltd v The Sec'y of State for Health,*[27] the High Court of Justice of England and Wales, Queen's Bench Division, referred a question to the Court of Justice whereby it inquired whether Article 20 of the Tobacco Products Directive was wholly or partly invalid because it (i) violated the principle of equality and/or unlawfully distorted

[25] *See generally* Tobacco Products Directive (not subjecting electronic cigarettes to the flavorings ban applicable to other tobacco products under art. 7).
[26] *E.g.*, Tobacco Products Directive art. 20(2) (setting forth a notification system specific to electronic cigarettes).
[27] Case C-477/14, *Pillbox 38 (UK) Ltd v The Sec'y of State for Health*, ECLI:EU:C:2016:324 (May 4, 2016).

competition, (ii) violated the principles of proportionality and legal certainty, (iii) violated the principle of subsidiarity, or (iv) violated manufacturers' and retailers' rights under Articles 16 and 17 of the Charter of Fundamental Rights of the European Union (the "**EU Rights Charter**").[28]

First, the claim of a violation of the principle of equality and free competition rested on the allegation that electronic cigarettes, though less harmful than traditional tobacco products to some extent, were subject to allegedly less favorable treatment than traditional tobacco products under the Tobacco Products Directive.[29] In analyzing this claim, the Court of Justice noted that it has previously held "that the principle of equal treatment requires that comparable situations must not be treated differently and different situations must not be treated in the same way unless such treatment is objectively justified."[30] Here, the Court of Justice found that electronic cigarettes were not similarly situated to traditional tobacco products for several reasons, including that they differed in (i) their composition (particularly with respect to the inclusion of tobacco), (ii) their physical mechanism for consumption (*i.e.*, combustion of tobacco vs vaporization of liquids), and (iii) the degree to which the health risks associated with both types of products are understood.[31] Based on those different characteristics, the Court of Justice ruled that electronic cigarettes and traditional tobacco products were not similar enough for their disparate treatment under the Tobacco Products Directive to amount to a violation of the principle of equality.[32] Relatedly, the Court of Justice found that the relevant arguments concerning the claim of alleged breach of free competition did not contain elements that were independent from

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[28] *Id.* at para. 13.
[29] *Id.* at para. 34.
[30] *Id*. at para. 35 (citations omitted).
[31] *Id.* at paras. 36-41.
[32] *See id*. at paras. 42-43, 45.

those of the claim concerning the principle of equality.[33] Consequently, the breach of free competition claim also failed.[34]

Second, the claim of a violation the principles of proportionality and legal certainty rested on the allegation that electronic cigarettes were perhaps beneficial, but certainly less harmful that other tobacco products, and therefore should not have been the subject of any rules, or to rules that were not comparable or stricter than those applicable to traditional tobacco products.[35] In addition, the claim rested on the allegation that the measures adopted in Article 20 of the Tobacco Products Directive were not subject to an impact assessment.[36]

As the Court of Justice stated, the EU legislature enjoys broad discretion when taking actions involving "political, economic and social choices."[37] Therefore, such actions will be upheld unless "the measure is manifestly inappropriate having regard to the objective which the competent institutions are seeking to pursue."[38] Moreover, in accordance with the precautionary principle, the EU legislature may adopt protective measures with respect to serious health risks that are probable but whose existence is uncertain if "the likelihood of real harm to public health persists should the risk materialize."[39]

In the case at hand, there was evidence that electronic cigarettes could lead to nicotine addiction and to the eventual transition to traditional tobacco, as well as to damage resulting from the inhalation of toxicants, and to damage by exposure to toxicants in ways other than

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[33] *Id*. at para. 44.
[34] *Id*. at para. 44-45.
[35] *Id*. at para. 47.
[36] *Id*.
[37] *Id*. at para. 49.
[38] *Id*.
[39] *Id*. at para. 55.

inhalation (such as accidental consumption by children).[40] Moreover, the evidence suggesting that electronic cigarettes were effective smoking cessation devices was limited and did not allow for that conclusion to be drawn.[41] Further, at the time of the adoption of the Tobacco Products Directive, Member State regimes regulating electronic cigarettes were varied, which made them liable to become obstacles to the free movement of goods.[42] Finally, the EU Legislature's action was consistent with meeting its commitment under the World Health Organization Framework Convention on Tobacco Control ("**FCTC**"), in relation to which the parties to the Convention vowed to consider prohibiting or regulating electronic cigarettes.[43] Based in part on the foregoing, the Court of Justice held that Article 20 of the Tobacco Products Directive was not manifestly inappropriate in contravention of EU law and did not violate the precautionary or proportionality principles.[44]

Further, the Court held that the fact that Article 20(2) of the Tobacco Products Directive required notification about nicotine dosage that consumers would intake under normal conditions was not vague enough to violate the principle of legal certainty, particularly given that it was within the EU legislature's discretion and authority to adopt broad language that would be clarified by subsequent Commission implementing acts.[45]

Third, the Court noted that Article 20 of the Tobacco Products Directive needed to be reviewed in light of the principle of subsidiarity set forth in Article 5(3) of the Treaty on European Union ("**TEU**") because Article 20 concerned the improvement of the

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[40] *Id.* at paras. 50, 52.
[41] *Id*. at para. 53.
[42] *Id*. at paras. 57-58.
[43] *Id*. at para. 59.
[44] *See id*. at paras. 60-61, 80.
[45] *Id*. at paras. 76-79.

functioning of the internal market, which is not an area of exclusive EU competence.[46] Here, the Court held that the discrepancies in the laws of Member States concerning the regulation of electronic cigarettes were such that EU action in that regulatory area was consistent with the principle of subsidiarity.[47]

Finally, the Court noted that Article 16 of the EU Rights Charter affords the right to "exercise an economic or commercial activity," but that freedom is not unrestricted and may be subject to limitations in service of the public interest.[48] The Court then held that the advertising restrictions imposed by Article 20 of the Tobacco Products Directive did not violate Chapter 16 of the EU Rights Charter given that they do not affect manufacturers' ability to manufacture their products, the restrictions' proportionality, and the enactment of Article 20 of the Tobacco Products Directive in a manner consistent with the requirements of the EU Rights Charter.[49]

The Court similarly rejected the challenge based on Chapter 17 of the EU Rights Charter, which concerned here the interference with intellectual property rights, holding that the operation of Article 20 of the Tobacco Products Directive left such rights essentially intact and any resulting interference was proportional.[50]

1.2. Introduction to US Federal Regulation of Electronic Cigarettes

The US federal law relevant to the regulation of tobacco products is the Food, Drug, and Cosmetic Act ("**FDCA**"),[51] as amended by the Family Smoking Prevention and Tobacco

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[46] *Id*. at paras. 144-149.
[47] *See id*. at para. 150.
[48] *Id*. at paras. 154-158.
[49] *Id*. at paras. 159-162.
[50] *Id*. at paras. 163-165.
[51] 21 U.S.C. §§ 301-399.

Control Act of 2009 (the "**Tobacco Control Act**").[52] Based on its terms and definitions, the FDCA does not explicitly regulate electronic cigarettes.[53] However, the FDCA contains a provision broadly extending the application of the FDCA to "tobacco products that the [Secretary of the Department of Health and Human Services] by regulation deems to be subject to" the FDCA.[54]

The Secretary of the Department of Health and Human Services delegated that regulatory authority to the Commissioner of a subsidiary agency, the U.S. Food and Drug Administration ("**FDA**").[55] The FDA has made use of that authority by promulgating final rules (the "**FDA Tobacco Rules**")[56] that broaden the definition of "tobacco products" under the FDCA to include nicotine-containing electronic cigarettes.[57] Although the agency rulemaking process is not subject to the same direct lobbying pressures that legislators face when making laws, the FDA was required to consider public comments on its proposed rules and provide rationales for its regulatory choices. In all, the FDA synthetized individual comments submitted to it into 304 general comments that it addressed throughout the FDA Tobacco Rules.

Ultimately, the FDA's rulemaking process, similarly to an extent to the EU Directive, resulted in a decision not to apply to electronic cigarettes the full regulatory regime that was already in existence for traditional tobacco products. Selected key provisions of the FDA Tobacco Rules that were made applicable to electronic cigarettes are discussed in

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[52] Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. 111-31, 123 Stat. 1776 (2009), https://www.congress.gov/bill/111th-congress/house-bill/1256/text.
[53] *See* 21 U.S.C. § 387.
[54] 21 U.S.C. § 387a.(b).
[55] *Jooce v. Food & Drug Admin.*, 981 F.3d 26, 27 (D.C. Cir. 2020), cert. denied, 141 S. Ct. 2854 (2021).
[56] FDA Tobacco Rules, 81 Fed. Reg. 28973 (May 10, 2016).
[57] 21 U.S.C. § 301(rr); 21 C.F.R. § 1100.1-.2; FDA Tobacco Rules, 81 Fed. Reg. 28973, 29043 (response to comment 172), 29048 (response to comment 183).

subsequent sections, including several concerning the manufacturing and marketing of such products.

In addition, the FDA Tobacco Rules made applicable to electronic cigarettes the FDCA's three-track pre-market authorization requirement, which is the legal process whereby persons introducing into interstate commerce electronic cigarettes that were not already in the market as of February 15, 2007, must seek pre-approval from the FDA.[58] The three tracks include (i) a track to be followed by manufacturers of "modified risk products," which are those that are "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products",[59] (ii) a track to be followed by manufacturers of products "intended to be used for the treatment of tobacco dependence, including smoking cessation",[60] and (iii) a track to be followed by all other manufacturers.[61] Due to the novelty of electronic cigarettes, that pre-market authorization requirement covered most electronic cigarettes being sold when the Final FDA Tobacco Rule came into effect in 2016; and it continues to cover even more products today as the industry continues to innovate and differentiate its product offerings.

1.2.1. Selected Legal Challenges Against the FDCA and the FDA Tobacco Rules

Before proceeding to the discussion of the FDA Tobacco Rules, it is apt to discuss *Nicopure Labs, LLC v. Food & Drug Admin.* [62] There, the United States Court of Appeals for the District of Columbia considered an appeal in which a group of electronic cigarette

[58] 21 U.S.C. § 387j-k.
[59] 21 U.S.C. § 387k(a).
[60] 21 U.S.C. § 387k(c).
[61] *See* 21 U.S.C. § 387j.
[62] 944 F.3d 267, 272 (D.C. Cir. 2019).

manufacturers and advocacy groups challenged the validity of the FDA Tobacco Rules by focusing on the legality of its pre-market authorization requirements. It is no surprise that the challenge targeted the pre-market authorization requirements because, as mentioned above, products that do not meet those requirements are prohibited from being sold in the United States. Therefore, obtaining the invalidation of those requirements would have allowed the challengers to sell their electronic cigarette products without violating the FDA Tobacco Rules or the FDCA.

The legal challenge consisted of three main arguments, discussed in turn. The first argument alleged that the FDA "violated the Tobacco Control Act and the Administrative Procedure Act (APA) by not providing an easier premarket authorization pathway for e-cigarettes."[63] In other words, the alleged violation rested on the application to electronic cigarettes of the pre-market authorization system already in existence for traditional tobacco products. The Court rejected this argument by finding that the health risks posed by electronic cigarettes, which were not well-understood, justified the FDA's application of the existing pre-market authorization requirements to place on manufacturers the burden of establishing that the characteristics of the products they intend to market are consistent with public health requirements.[64]

The second challenge alleged that the pre-market authorization standards applicable to modified risk products violated the First Amendment because they restrict manufacturers' ability to communicate truthful and non-misleading statements concerning electronic cigarettes.[65] However, the Court held that the application of the modified risk approval

[63] *Nicopure* at 271.
[64] *See id.*
[65] *Nicopure* at 271.

track to electronic cigarettes was supported by data concerning health risks associated with nicotine, and that, consequently, requiring electronic cigarette manufactures to substantiate their claims that their products are safer than traditional tobacco products before marketing them does not violate the First Amendment.[66]

Finally, the third challenge alleged that the prohibition of distributing free samples of tobacco products, made applicable to electronic cigarettes by the FDA Tobacco Rules, also violated the First Amendment in that it impermissibly restricted expressive conduct by manufacturers.[67] The Court similarly rejected this argument, holding that distribution of free samples does not constitute expressive conduct protected by the First Amendment, as well as that the distribution prohibition was in any case not aimed at the suppression of expressive conduct so as to invoke the First Amendment's protection.[68]

It is also apt to present an interesting aspect of a separate unsuccessful challenge of the validity of the FDA Tobacco Rules. In the case *Jooce v. Food & Drug Admin.*,[69] a group of manufacturers and retailers of electronic cigarettes and a non-profit organization challenged the FDA Tobacco Rules alleging they were promulgated in violation of the US Constitution's Appointments Clause.[70] The Appointments Clause requires that "all . . . Officers of the United States be appointed by the President by and with the Advice and Consent of the Senate."[71] As previously noted, the FDCA vests regulatory authority under that law on the Secretary of the Department of Health and Human Services, which authority the Secretary delegated to the FDA Commissioner, who, in turn, delegated the authority to

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[66] *Id.* at 271-72.
[67] *Id.* at 271.
[68] *Id.* at 272.
[69] 981 F.3d 26, 27.
[70] *Id.* at 27.
[71] *Id.* at 28 (internal quotations omitted) (citing U.S. Const. art. II, § 2, cl. 2).

the FDA Associate Commissioner for Policy.[72] In accordance with that delegated authority, it was the FDA Associate Commissioner for Policy (who is not an officer of the US appointed by the US President) who promulgated the FDA Tobacco Rules. Thus, the challengers of the law argued that the FDA Tobacco Rules were void *ab initio*, given that their promulgation was not made by a constitutionally appointed officer.[73]

However, the Court held that, even assuming that the FDA Associate Commissioner for Policy lacked the authority to promulgate the FDA Tobacco Rules, the challenge against them failed because the FDA Commissioner, who is an officer appointed pursuant to the Appointments Clause, ratified the adoption of the FDA Tobacco Rules.[74] That ratification, the Court held, served to cure any purported defects concerning the promulgation of the FDA Tobacco Rules under the Appointments Clause, even though the ratification occured after the FDA Tobacco Rules came into effect and after the case at hand was filed.[75]

1.3. Introduction to California Regulation of Electronic Cigarettes

In addition to the regulation by the federal government discussed above, this thesis will present and discuss California regulations, as appropriate. There are two main reasons for the inclusion in this thesis of California regulations. First, the relationship between the federal government and state governments in the United States relating to health- and tax-related regulations is not entirely dissimilar from that of the European Union and national governments in that US state governments and EU national governments retain authority to issue those types of regulations. Second, even setting aside that distribution of regulatory

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[72] *Id.* at 27-28.
[73] *Id.* at 28.
[74] *Jooce* at 29.
[75] *Id.*

authority, California regulations are informative because they are enacted with the intent to influence the consumer behavior and protect the health of approximately 39 million residents[76], which represents a population larger than that of all but four of the twenty-seven countries in the European Union.[77]

Regulatory actions in California concerning electronic cigarettes are wide-ranging. Notably, in California, lawmaking is not the exclusive domain of the government because California electors may also take those actions directly through (i) the adoption of initiative measures to propose and enact statutes and constitutional amendments (or so-called propositions), as provided for under Article II, Section 8, of the California Constitution, as well as (ii) the passing of referendums to approve or reject statutes enacted by the government, as provided for under Article II, Section 9, of the California Constitution. Both types of measures have played a role in the regulation of electronic cigarettes.

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[76] 2020 Census Apportionment Results, Table 2. Resident Population for the 50 States, the District of Columbia, and Puerto Rico: 2020 Census, available at https://www.census.gov/data/tables/2020/dec/2020-apportionment-data.html.

[77] *See* Eurostat, *Population and Population Change Statistics* (July 5, 2021) (Table 1: Demographic balance, 2020), https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Population_and_population_change_statistics#Population_change_at_national_level.

2. Regulations Relating to Key Ingredients of Electronic Cigarettes

Regulating which ingredients may be contained in electronic cigarettes that are introduced to national markets serves the purpose of guaranteeing that electronic cigarettes do not contain harmful chemicals, regardless of whether the devices are manufactured nationally or abroad. Conversely, absence of regulation could result in consumers of electronic cigarettes being exposed to different types, and concentrations or doses of, potentially harmful chemicals, such as nicotine, as they inhale vaporized liquids when they use these products.

That concern has been well-founded since the times in which regulatory action concerning electronic cigarettes was first considered and implemented because several studies have called attention to the potential harmful effects of electronic cigarette liquids. For example, a National Consumer Institute study from France found that some cartridges contained as much formaldehyde as did conventional cigarettes, while others contained traces of potentially harmful chemicals, such as acrolein and acetaldehyde.[78] More recent animal model studies also suggest that aerosolized chemicals in electronic cigarette vapors may indeed increase the likelihood of developing cancer and other illnesses, despite the currently accepted understanding that aerosolized nicotine in non-traditional tobacco products do not cause such effects.[79] Moreover, the CDC continues to hold the view that

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[78] *See, e.g.*, McPartland, *supra* note 1; US Env't Prot. Agency, *Acrolein*, https://www.epa.gov/sites/default/files/2016-08/documents/acrolein.pdf (last visited Jan. 15, 2022) (Acrolein "is toxic to humans . . . inhalation exposure may result in upper respiratory tract irritation and congestion."); US Env't Prot. Agency, *Acetaldehyde*, https://www.epa.gov/sites/default/files/2016-09/documents/acetaldehyde.pdf (last visited Jan. 15, 2022) ("Acute (short-term) exposure to acetaldehyde results in effects including irritation of the eyes, skin, and respiratory tract. . . . Acetaldehyde is considered a probable human carcinogen. . . .").

[79] *See, e.g.*, Moon-shong Tang et al., *Electronic-Cigarette Smoke Induces Lung Adenocarcinoma and Bladder Urothelial Hyperplasia in Mice*, 116 Proceedings of the Nat'l Acad. of Scis. of the US, 21727–21731 (2019), https://www.pnas.org/content/116/43/21727.long.

the vapor of aerosolized liquid produced by electronic cigarettes may contain, in addition to nicotine, (i) flavoring such as diacetyl, a chemical linked to a serious lung disease, (ii) volatile organic compounds, (iii) cancer-causing chemicals, and (iv) heavy metals such as nickel, tin, and lead.[80]

That concern over exposing citizens to dangerous substances comes not only from the government, but also, at least in California, from the public itself. In 1986, California voters took direct action to enact the Safe Drinking Water and Toxic Enforcement Act by passing Proposition 65 at the ballot.[81] The Act, codified in the Health and Safety Code, is meant to the people of California "against chemicals that cause cancer, birth defects or other reproductive harms."[82] Under the Act, the governor of California must cause to be published an official list of such chemicals at least annually.[83] And no person or entity "may knowingly and intentionally" expose citizens to a chemical on that list without displaying a specified warning.[84] Nicotine is on the current Proposition 65 list.[85]

Considering the foregoing, it is appropriate for governments to regulate ingredients in electronic cigarettes to ensure that consumers are not exposed to dangerous substances at levels that are known to be harmful to the health (*e.g.*, those that are or may be carcinogenic). Because the ingredient that may be contained in electronic cigarette liquids

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[80] CDC, *About Electronic Cigarettes (E-Cigarettes)*, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html (last visited Feb. 1, 2022).
[81] Cal. Office of Env't and Hazard Assessment, *Proposition 65 Law and Regulations*, https://oehha.ca.gov/proposition-65/law/proposition-65-law-and-regulations (last visited Feb. 5, 2022).
[82] *Proposition 65*, sec. 1, https://oehha.ca.gov/media/downloads/proposition-65/general-info/prop65ballot1986.pdf.
[83] CAL. HEALTH & SAFETY CODE § 25249.8.
[84] CAL. HEALTH & SAFETY CODE § 25249.6.
[85] Chemicals Known to the State of California to Cause Cancer Or Reproductive Toxicity, OFFICE OF ENVIRONMENTAL AND HAZARD ASSESSMENT, CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY (December 31, 2021), https://oehha.ca.gov/media/downloads/proposition-65//p65chemicalslistsinglelisttable2021p.pdf.

are too great to address and consider in this thesis, the following two sections will focus specifically on two types of ingredients: (i) nicotine and (ii) flavoring substances.

2.1. Regulations Specific to the Use of Nicotine

Nicotine's documented action on the brain results in addiction, which generally develops more rapidly in minors than in adults.[86] In addition to causing addiction, nicotine has been documented to generate multiple negative effects on the health of young users, including affecting brain development and cognition.[87] Furthermore, "[u]sing nicotine in adolescence can also increase risk for future addiction to other drugs".[88] This potential for addiction includes the risk that young users may eventually transition to the use of traditional tobacco products (*i.e.*, that electronic cigarettes may be gateway devices).[89] If that proves to be true in cases where minors switch to consuming traditional tobacco products, then the effects on those individuals' health could be even more damaging.

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[86] U.S. SURGEON GENERAL, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL (2016), 99, https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

[87] *Id.*; As required by the FDCA, the FDA has published a list of known substances in tobacco products that are associated by health harms; nicotine appears on that list identified as being both addictive and a reproductive or developmental toxicant. – FDA, *Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List*, https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list (last visited Feb. 1, 2022).

[88] U.S. SURGEON GENERAL, SURGEON GENERAL'S ADVISORY ON E-CIGARETTE USE AMONG YOUTH (2018), 1, https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf.

[89] *See, e.g.*, Tobacco Products Directive, recital 43 ("Electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking."); Heewon Kang & Sung-il Cho, Longitudinal Transitions of Cigarettes and Electronic Nicotine Delivery Systems Among Adolescents: Construction of a Retrospective Cohort using Recall Data from a Cross-sectional Sample, Tobacco Induced Diseases, TOBACCO INDUCED DISEASES, Dec. 2020, at 1 ("Based on the recall data of a cross-sectional sample, we demonstrate that ENDS experimentation increases the likelihood of cigarette smoking initiation."), http://www.tobaccoinduceddiseases.org/Longitudinal-transitions-of-cigarettes-and-electronic-nicotine-ndelivery-systems,128488,0,2.html.

Other than nicotine-related effects, there may be other deleterious impacts on the health of electronic cigarette users that are currently not known. The reason for that is that electronic cigarettes are a relatively new product in the market, as compared to traditional cigarettes, and, consequently, there is a lack of substantial long-term studies into electronic cigarettes.[90] For example, although further research is needed to validate causation, some studies suggest that electronic cigarette users who do not smoke traditional cigarettes may be at an increased risk of suffering from asthma, chronic obstructive pulmonary disease and asthma-COPD, as compared to the general population who have never used either products.[91]

Based on the foregoing health concerns, there is clear justification for the relevant authorities to regulate electronic cigarettes in order to protect public health. In addition, pre-regulation data suggests that concerted action in this area was also required in order to ensure consistent manufacturing standards were used in connection with the production of electronic cigarettes. For example, an EU Commission impact assessment conducted before the Tobacco Products Directive came into effect reported cases in which electronic cigarette cartridges' nicotine content differed from levels stated in their packages.[92] The FDA also recognized that variability in electronic cigarette liquids in its FDA Tobacco Rules.[93] The existence of such discrepancies are also supported by the findings of some

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[90] Sakshi Sapru et al., *E-cigarettes Use in the United States: Reasons for Use, Perceptions, and Effects on Health*, BMC PUBLIC HEALTH, Oct. 2020, at 1 https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-09572-x.

[91] Emine Bircan et al., *Electronic Cigarette Use and Its Association with Asthma, Chronic Obstructive Pulmonary Disease (COPD) and Asthma-COPD Overlap Syndrome Among Never Cigarette Smokers*, TOBACCO INDUCED DISEASES, Sept. 2021, at 1, http://www.tobaccoinduceddiseases.org/Electronic-cigarette-use-and-its-association-with-asthma-nchronic-obstructive-pulmonary,142579,0,2.html.

[92] *See* Library of the European Union, *Briefing on Electronic Cigarettes*, 3 (2013), https://www.europarl.europa.eu/RegData/bibliotheque/briefing/2013/130494/LDM_BRI(2013)130494_REV3_EN.pdf.

[93] FDA Tobacco Rules at 28984 (response to comment 4).

studies,[94] some of which also found that some electronic cigarette cartridges labeled nicotine-free actually contained traces of the substance.[95] Those discrepancies threaten public health not only because consumers may develop addition if they are exposed to nicotine through products that are supposed to be nicotine-free but are not, but also because nicotine in higher concentrations than expected by consumers based on incorrect packaging may result in accidental poisonings.

The sections that follow discuss how key EU and US electronic cigarette regulations specific to the use of nicotine.

2.1.1. EU Regulations Relating to the Use of Nicotine

Article 20 of the Tobacco Products Directive sets forth a nicotine limit of 20 mg/ml, and maximum aggregate liquid volume of 10 ml for refill containers and 2 ml for single-use electronic cigarettes and cartridges.[96] Further, electronic cigarettes must be designed such that nicotine is consistently delivered at consistent levels.[97]

Based on Recital 38 of the Tobacco Products Directive, the above-mentioned level of nicotine concentration was adopted because it "allows for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette during the time needed to smoke such a cigarette." And Recital 39 of the Tobacco Products Directive explains that requiring that electronic cigarettes deliver nicotine at consistent levels "is

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[94] *E.g.*, Amelia Taylor et al., *A Review of Nicotine-containing Electronic Cigarettes—Trends in Use, Effects, Contents, Labelling Accuracy and Detection Methods*, DRUG TESTING AND ANALYSIS, Jan. 2021, at 242-260, https://analyticalsciencejournals.onlinelibrary.wiley.com/doi/full/10.1002/dta.2998; Maciej L. Goniewicz et al, *Nicotine Levels in Electronic Cigarette Refill Solutions: A Comparative Analysis of Products from the US, Korea, and Poland*, INT'L JOURNAL OF DRUG POLICY, June 2015, at 1, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4457636/.

[95] *Id.*

[96] Tobacco Products Directive art. 20(3)(a)-(b).

[97] Tobacco Products Directive art. 20(3)(f).

necessary for health protection, safety and quality purposes, including to avoid the risk of accidental consumption of high doses." In other words, Article 20's nicotine-related provisions are aimed at making electronic cigarette no more harmful than traditional cigarettes consumed under normal circumstances with respect to the ingestion of nicotine.

2.1.2. US Federal Regulations Relating to the Use of Nicotine

Perhaps surprisingly given the known health risks associated with nicotine consumption, nicotine content is not subject to any regulation under either the FDCA or the FDA Tobacco Rules. In the FDA Tobacco Rules, the FDA stated that "[m]any comments expressed concern about the increase in nicotine poisonings due to accidental ingestion of e-liquids and offered suggestions to address this issue: (1) Set a maximum nicotine content level for e-liquids" among others.[98] And although the FDA acknowledged that it had in the past "expressed similar concerns about the increase in nicotine poisonings," it announced that it would defer action concerning this topic for subsequent regulations and guidance.[99] Ostensibly, the FDA would have to take nicotine toxicity into account as it reviews pre-market authorization applications to determine whether a product is safe enough to be introduced to the market, but the FDA has not issued guidance setting forth a bright line past which nicotine concentration will be considered *per se* unsafe.

Congressional records show that in October 2019 (during the 116th Congress), Representative Raja Krishnamoorthi introduced the END ENDS Act of 2019 in Congress.[100] The Act aimed to amend the FDCA to introduce a nicotine limit of 20

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[98] FDA Tobacco Rules at 29056 (Comment 222).
[99] FDA Tobacco Rules at 29056 (Response to comment 222).
[100] H.R. 4624, 116th Cong. (2019), https://www.congress.gov/bill/116th-congress/house-bill/4624/text?r=27&s=1.

milligrams per milliliter in electronic cigarette liquids, or a lower limit that the Secretary of the Department of Health and Human Services determined to be minimally addictive or non-addictive.[101] The Act was not acted on before the term of the 116th Congress expired in January 2021 and was therefore archived. In May 2021, Representative Krishnamoorthi re-introduced the Act as part of the 117th Congress, and it has not been the subject of any further substantive action as of the time of submission of this thesis.[102]

In the wake of the lack any regulation concerning the maximum concentration of nicotine in electronic cigarettes, a 2018 study identified a trend whereby the average nicotine concentration in such products steadily increased between 2013 and 2017.[103] And the higher concentration products tended to account for the highest proportion of total market sales.[104] As of 2022, the liquid in a line of high-nicotine electronic cigarettes sold by manufacturer Juul Labs in the US contains as much as 59 milligrams of nicotine per milliliter (approximately 40 milligrams of nicotine per electronic cigarette),[105] which is approximately equivalent to the nicotine content of an entire pack of 20 traditional cigarettes.[106]

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[101] Id. § 4(a).
[102] H.R. 3051, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/house-bill/3051/text?q=%7B%22search%22%3A%5B%22%5C%22nicotine%5C%22%22%2C%22%5C%22nicotine%5C%22%22%5D%7D&r=2&s=1.
[103] Alexa R. Romberg et al., *Patterns of nicotine concentrations in electronic cigarettes sold in the United States, 2013-2018*, DRUG AND ALCOHOL DEPENDENCE, July 2019, at 1, 1-7, https://www.sciencedirect.com/science/article/pii/S0376871619302571.
[104] *Id.* at 3.
[105] Juul, *What Is the Size of a JUULpod?*, https://www.juul.com/resources/what-is-the-size-of-a-juulpod (last visited Feb. 8, 2022).
[106] Nicole Kuiper et al., *Trends in Manufacturer-Reported Nicotine Yields in Cigarettes Sold in the United States, 2013–2016*, PREVENTING CHRONIC DISEASE, Nov. 2020, at 1 (observing that the average nicotine content of a traditional high-nicotine cigarette is between 0.91 and 3 milligrams), https://www.cdc.gov/pcd/issues/2020/20_0205.htm.

Considering the foregoing, the federal government should act to regulate in this area, whether through the enactment of the END ENDS Act or otherwise. The current regulatory stance whereby several aspects of electronic cigarette manufacturing and sale are regulated, but not the key chemical substance the addiction to which makes those products attractive in the first place is not well-founded.

2.2. Regulations Specific to the Use of Flavorings

Electronic cigarettes are available in a plethora of flavors. That is no surprise given that research concerning the use of electronic cigarettes by the youth shows that flavorings is one of most common reasons for use of those products, and may play an important role in youths' decision to develop an interest in using those products in the first place.[107] For example, the US Tobacco Survey of 2021 shows that 84.7% of overall electronic cigarette consumers use flavored electronic cigarettes, with the most common flavors being "fruit, followed by candy, desserts, or other sweets; mint; and menthol."[108] These preferences are factors that should play a role in the design of effective regulations aimed at reducing the rate of consumption of electronic cigarettes, particularly with respect to young consumers.

In fact, this common-sense ban already applies to certain traditional tobacco products.[109] That is because, in the past, flavoring additives caused serious public health consequences, which led to them being prohibited in cigarettes. Yet electronic cigarettes are currently allowed to use that same tactic to attract young consumers. Prohibiting the use of flavoring

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[107] *See, e.g.*, U.S. SURGEON GENERAL, *supra* note 88, at 87.
[108] Eunice Park-Lee et al., *E-Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey*, United States, 2021, 70 MORBIDITY AND MORTALITY WEEKLY REPORT 1387, 1387 (2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7039a4.htm.
[109] 21 U.S.C. § 387g(a)(1)(A) (US ban on cigarette flavorings); Tobacco Products Directive art. 7(1) (EU ban on tobacco products flavorings).

additives that make electronic cigarettes more palatable could reduce youth interest in the devices.[110]

Banning these additives would counteract the youth's particular susceptibility to increases in consumption because of the availability of attractive flavors. In addition, banning the use of flavoring may aid the effectiveness of other regulatory measures, such as price increases through taxation, because it would limit the ways in which manufactures may differentiate their products in the market. This, in turn, would aid reducing continued sales tied to brand switching in the face of higher prices due to consumer preferences and perceptions.[111]

Regulations concerning the use of flavorings in the EU, US and California are discussed below.

2.2.1. EU Regulations Relating to the Use of Flavorings

As discussed, flavorings are understood to play a role in enticing the youth to purchase electronic cigarettes. Based on that, and given that a policy goal of the Tobacco Products Directive is to reduce consumption of tobacco-related products by young people, then banning the use of flavorings would be one of the tools available to legislators to employ in service of accomplishing that goal. However, the Tobacco Products Directive includes a ban on characterizing flavors that is applicable only to "tobacco products,"[112] which are

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[110] *See, e.g.*, Matthew E. Rossheim et al., *Cigarette Use Before and After the 2009 Flavored Cigarette Ban*, 67 J. of Adolescent Health 432, 432-437 (2020) (analyzing the presenting the significant decrease in the likelihood of youth smoking after the 2009 US ban on flavored cigarettes), https://pubmed.ncbi.nlm.nih.gov/32674967/; *see also* Charles J. Courtemanch et al., *Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use*, AM. J. PREVENTIVE MEDICINE, May 2017, at 1-13, https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC5401634&blobtype=pdf.

[111] *See* WHO, *WHO Technical Manual on Tobacco Tax Policy and Administration*, 23-24 (2021) [hereinafter *WHO Tobacco Tax Manual*], https://www.who.int/publications/i/item/9789240019188.

[112] Tobacco Products Directive art. 7(1). It must be noted that the Tobacco Products Directive's definition of tobacco products is best understood as an affirmative choice to exclude electronic cigarettes from regulation other than as set forth specifically for such products under Article 20. In contrast, the US definition of "tobacco product," which pre-existed the Tobacco Products Directive, is broader because it

defined as "products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not."[113] As a consequence of that definition, electronic cigarettes are generally not tobacco products, and consequently not subject to the flavorings ban, because while electronic cigarettes contain nicotine, they do not include tobacco.

In light of the foregoing, the set of rules in Article 20 of the Tobacco Products Directive can be said to not be as extensive as they could reasonably be to reduce youth consumption of electronic cigarettes because it does not include a ban on flavoring additives. In fact, leaving to Member States the decision whether to ban flavorings raises the question why, if flavorings are known to attract youth use, did the EU choose not to take immediate action to prevent EU citizens from becoming accustomed to these nicotine-containing products, which, as discussed, (i) is a substance proven to negatively impact both public health and individual quality of life and (ii) may serve as a gateway to transition to the use of more harmful traditional tobacco products.

2.2.2. US Federal Regulations Relating to the Use of Flavorings

The FDCA imposes a ban on the use of flavorings in traditional cigarettes, except for tobacco and menthol.[114] Although the FDA adopted the FDA Tobacco Rules to regulate aspects of the manufacturing of electronic cigarettes, the FDA did not extend to such products in the FDA Tobacco Rules the FDCA's flavorings ban. However, in 2020, partially due to recognizing the rise in the consumption rates of electronic cigarettes among American youth, the FDA promulgated its Enforcement Priorities for Electronic Nicotine

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includes "any product made or *derived* from tobacco that is intended for human consumption. . . ." (21 U.S.C. § 321(rr)(1) (emphasis mine)), which provides the FDA discretion to apply traditional tobacco regulations to nicotine-containing electronic cigarettes (even if they do not contain tobacco), given that nicotine is a tobacco derivative.

[113] Tobacco Products Directive art. 2(4).

[114] 21 U.S.C. § 387g(a)1(A).

Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised) (the "**ENDS Guidance**").[115]

In the ENDS Guidance, the FDA announced it was prioritizing its regulatory efforts to focus on taking off the market any electronic cigarettes that contained flavorings (other than tobacco and menthol) and that did not comply with the pre-market authorization requirements set forth in the FDCA. In other words, the FDA's enforcement priorities as set forth in the ENDS Guidance may be understood as essentially instituting an indirect flavoring ban applicable to "cartridge-based" electronic cigarettes.[116]

Two aspects of that ban are worth calling attention to. First, it does not "include completely self-contained, disposable products."[117] In other words, it left open a loophole whereby manufacturers and sellers could take comfort in the deprioritized enforcement against disposable electronic cigarettes.

Second, if it is to be considered a flavoring ban at all, it cannot be ignored that it is indirect for three reasons. First, as mentioned above, there is no explicit direct flavoring ban in the FDCA or the FDA Tobacco Rules on tobacco products, except for traditional cigarettes. Second, all electronic cigarettes that do not comply with the pre-market authorization would technically be in the market in violation of the law, so the ENDS Guidance merely places flavored electronic cigarettes at the top of the list of non-compliant products for enforcement purposes. Finally, third, because there is no direct flavorings ban, it is

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[115] FDA, CENTER FOR TOBACCO PRODUCTS, FDA-2019-D-0661, ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION (REVISED) (2020) [hereinafter *ENDS Guidance*], https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market.
[116] *Id.* at 9.
[117] *Id.* at 9 n.21.

technically possible for persons to obtain pre-market authorization to sell flavored electronic cigarettes, if they comply with all applicable legal requirements. In other words, a needed flavoring ban is yet to be implemented, which leaves an opportunity open for federal and state action on the topic.

2.2.1. California Regulations Relating to the Use of Flavorings

California law does not address manufacturing requirements concerning the use of flavorings in electronic cigarettes because such regulations would be pre-empted by the FDCA.[118] As discussed above, the use of flavoring in electronic cigarettes without a pre-market authorization is currently subject to enforcement priority by the FDA under the ENDS Guidance. However, that priority represents, at best, an indirect flavoring ban that does not apply to disposable electronic cigarettes and still allows for the use of tobacco and menthol flavors.

In recognition of the effect of flavorings on product sales and absent concrete federal action, in August 2020, the governor of California signed California Senate Bill 793 ("**SB 793**"), which amends the California Health and Safety Code to prohibit retailers from selling tobacco products that contain components imparting a characterizing flavor.[119]

In accordance with SB 793, the definition of tobacco products for purposes of this flavoring restriction includes electronic cigarettes.[120] Therefore, to comply with this law, electronic

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[118] *See* 21 U.S.C. § 387p(a)(2) (preempting, as relevant here, any state or local regulation "with respect to a tobacco product . . . which is different from, or in addition to, any [FDCA] requirement . . . relating to tobacco product standards. . . .").
[119] 2020 Cal. S.B. No. 793, California 2019-2020 Regular Session, available at https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200SB793; The entry into force of SB 793 is currently on hold as explained following the discussion of the key operative provisions of the law.
[120] *Id*. § 1.

cigarettes cannot have any "distinguishable taste or aroma, or both, other than the taste or aroma of tobacco, imparted by a tobacco product or any byproduct produced by the tobacco product." SB 793, by way of example, specifically lists popular flavorings that would no longer be allowed under the law, including "tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice."

A rebuttable presumption that an electronic cigarette contains a characterizing flavor arises "if a manufacturer or any of the manufacturer's agents or employees, in the course of their agency or employment, has made a statement or claim directed to consumers or to the public that the tobacco product has or produces a characterizing flavor, including, but not limited to, text, color, images, or all, on the product's labeling or packaging that are used to explicitly or implicitly communicate that the tobacco product has a characterizing flavor." However, SB 793 explicitly provides that what may result in a violation of the law is the *actual* detectable "presence of a distinguishable taste or aroma, or both," rather than the mere use of a substance that may be understood to *potentially* impart a characterizing flavor or aroma.

Read together, those two provisions appear to create a loophole whereby a manufacturer could claim or suggest that its electronic cigarettes impart a popular characterizing flavor to support sales of those products, yet be insulated from liability under SB 793 if it can be established that the products do not actually impart a characterizing flavor despite the contrary claim or suggestion. To bolster compliance with SB 793 absent further legislative

action to close that loophole, the government of California may clearly signal that any such attempts to circumvent SB 793 will be prosecuted for false or misleading advertising.[121]

Notably, the most current report concerning the fiscal impact of SB 793 (*i.e.*, how state revenues are expected to be affected as a result of consumer behavior changes) estimated a total revenue loss of approximately $260 million.[122] Although that sum is not insignificant, it will be important to study how consumption levels change by demographic group to determine the effectiveness of this flavored-products ban, which is incremental to the existing federal action, with respect to reducing consumption of electronic cigarettes among the youth of California.

Notwithstanding that SB 793 is expected to be effective in general terms, as shown by the above-mentioned estimated decrease in state revenues in connection with the sale of tobacco-related products, SB 793 is currently the subject of a veto referendum that will take place on November 8, 2022.[123] If the proponents of the referendum obtain a majority of votes, SB 793 will not become effective, and the sale of flavored tobacco products may continue in California, subject only to the federal restrictions.

It is perhaps no surprise that industry opponents of bans on the sale of flavored tobacco products at the state level resorted to a veto referendum to attempt to overturn SB 793. That is because several courts, including in California, have already held that such bans are not pre-empted by the FDCA, which gives states regulatory authority to promulgate them. For

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[121] Prosecution could be conducted, for example, pursuant to CAL. BUS. & PROF. CODE § 17500, which makes it unlawful to sell products underpinned by the dissemination of any "circumstance or matter of fact" that is "untrue or misleading".

[122] *See* CAL. ASSEMB. COMM. ON APPROPRIATIONS, ANALYSIS ON S.B. 793 (2020), https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201920200SB793.

[123] Cal. Sec'y of State, *Qualified Statewide Ballot Measures*, https://www.sos.ca.gov/elections/ballot-measures/qualified-ballot-measures (last visited Feb. 6, 2022).

example, in *Neighborhood Mkt. Ass'n, Inc. v. Cty. of San Diego*,[124] the Court held that a sales ban of flavored products in an ordinance promulgated by the City of San Diego did not constitute a "tobacco product standard" subject to preemption under the FDCA because, although related to the products' ingredients, the ordinance concerned the *sale* of such products not their *manufacture*.[125]

In light of that jurisprudence, the best (and perhaps sole) opportunity to overturn SB 793 is thus provided by prevailing on the veto referendum. However, referendum's likelihood of success may be less than optimal for its proponents based on previous failed industry efforts to overturn a local flavorings ban. In 2017, the City of San Francisco, California, enacted a law banning flavored tobacco products.[126] Opponents of that law obtained enough signatures to require that the law be submitted to an approval referendum, which occurred in June 2018 and in which a resounding 68.39% of voters ratified the law.[127]

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[124] 529 F. Supp. 3d 1123, 1126 (S.D. Cal. 2021).
[125] 529 F. Supp. 3d 1123, 1131-35 (S.D. Cal. 2021); *see also Cal. Smoke & Vape Ass'n, Inc. v. Cty. of Los Angeles*, No. CV 20-4065 DSF (KSX), 2020 WL 4390384, at *6 (C.D. Cal. June 9, 2020) ("[A] flavored tobacco ban is not a regulation of tobacco product standards and therefore is not preempted.").
[126] CITY AND CNTY. OF SAN FRANCISCO, VOTER INFORMATION PAMPHLET & SAMPLE BALLOT (2018), 106, https://webbie1.sfpl.org/multimedia/pdf/elections/June5_2018.pdf.
[127] City and Cnty. of San Francisco, Dep't of Elections, *June 5, 2018 Election Results – Summary* (see results of Local Measure E), https://sfelections.sfgov.org/june-5-2018-election-results-summary (last visited Feb. 6, 2022).

3. Regulations Relating to Textual Health Warnings on Packaging of Electronic Cigarettes

Textual warnings help communicate the risks of smoking electronic cigarettes. As discussed, the addictive effects of some of the ingredients in electronic-cigarette cartridges, such as nicotine, are well documented. Therefore, at minimum, effective regulations should aim to clearly disclose those known risks to ensure that the public makes informed choices about smoking electronic cigarettes. In addition, it would be prudent to consider disclosing the possibility that electronic cigarettes might increase the likelihood of transitioning to the use of harmful traditional tobacco products. These rules are important to help protect public health, particularly considering the explosive rate at which use of electronic cigarettes has grown in past years.

As set forth below, the required warnings under the Tobacco Products Directive and the FDCA focus on nicotine's effects. That is consistent with the long known and understood risk of that substance. However, regulatory authorities may consider broadening the language of the warnings if future studies demonstrate that inhaling aerosolized liquids through electronic cigarettes is harmful to human health in ways independent from the action of nicotine in the system.

That flexibility to respond to the evolving science is built into California's warning system because systems are generally triggered based on the inclusion in any product of a substance that is known to be carcinogenic or to cause reproductive toxicity. And the official list of such substances that trigger a warning obligation must be updated at least once a year under state law.

3.1. EU Regulations Relating to Textual Health Warnings

Under Article 20(4)(b)(iii) of the Tobacco Products Directive, Member States must choose one of the following two health warnings, which must then be displayed on the packaging of electronic cigarettes: (i) "This product contains nicotine which is a highly addictive substance. It is not recommended for use by non- smokers." or (ii) "This product contains nicotine which is a highly addictive substance." The chosen warning must be displayed in accordance with the requirements of Article 12(2) of the Tobacco Products Directive[128], which sets forth the appropriate location and size of the warning.

3.2. US Federal Regulations Relating to Textual Health Warnings

Under the Final FDA Tobacco Rules, electronic cigarette packages must bear the following warning: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."[129] The waning must be clearly visible and cover at least 30% of each of the package's two principal displays.[130]

Such required warning must also be displayed on advertisements for electronic cigarettes. Neither the FDCA nor the Final FDA Tobacco Rules define the term "advertisement." But FDA has stated that the term "should be interpreted broadly and should be interpreted to include statements regarding the availability of tobacco products. . . . in or on, for example, . . . Internet Web pages. . . ."[131] Electronic cigarette manufacturers such as Juul Labs and

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[128] Tobacco Products Directive art. 20(4)(c).
[129] 21 C.F.R. § 1143.3(a).
[130] *Id.* This section sets with additional requirements pertaining to technical details, such as font type, size and color.
[131] FDA Tobacco Rules at 28973-01(response to comment 237).

blu eCigs have complied with that requirement by placing prominent warning banners at the top of their respective website's homepage.

Importantly, the legal basis of that electronic cigarette warning requirement may be ripe for challenge in court. This is because, although under a separate rule, the Final FDA Tobacco Rules imposed a similar warning requirement on cigars.[132] However, in *Cigar Ass'n of Am. v. United States Food & Drug Admin.*, the US Court of Appeals for the District of Columbia vacated the cigar warning rule as violating both the FDCA and the Administrative Procedure Act ("**APA**").[133] There, the plaintiffs sought the invalidation of the cigar warning requirement arguing that it was arbitrary and capricious in violation of applicable law.[134]

The Court explained that under the APA, which governs the manner in which US federal agencies may promulgate regulations, such regulations may be vacated when they are arbitrary and capricious, such as when "the agency failed to consider an important aspect of the problem before it, including any factor the agency must consider under its organic statute."[135] Under the FDA's organic statute, the FDCA, the agency is authorized to promulgate tobacco regulations that it (i) determines "would be appropriate for the protection of the public health," which determination must be made "with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account" the likelihood that such users will begin using and stop using such products, respectively.[136]

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[132] 21 C.F.R. § 1143.5.
[133] *Cigar Ass'n of Am. v. United States Food & Drug Admin.*, 964 F.3d 56, 65 (D.C. Cir. 2020).
[134] *Id.* at 61.
[135] *See id.* (internal quotations and citations omitted).
[136] 21 U.S.C, § 387f(d)(1).

The Court found that the FDA did not follow that FDCA mandate when imposing warning requirements on cigars because the Final FDA Tobacco Rules failed to "consider the impact of health warnings on smoking cessation and adoption rates."[137] Moreover, the Court noted that the Final Regulatory Impact Analysis of the Final FDA Tobacco Rules[138] explicitly stated that the FDA was not aware of any reliable evidence concerning the impact of warning labels on the use of cigars.[139] Based on the foregoing, the Court vacated the cigar warning rule.[140]

Problematically, the Final FDA Tobacco Rules similarly do not discuss the effect of warning on the adoption or cessation rates of electronic cigarettes. And the Final Impact Assessment's acknowledgment of the lack of evidence for textual warnings applied to the then-newly regulated products covered not only cigars, but also electronic cigarettes.[141] Therefore, relying on the precedent set by *Cigar Ass'n of Am.*, it may be possible for subsequent lawsuits to seek and obtain the invalidation of the warning rule applicable to electronic cigarettes.

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[137] *Cigar Ass'n of Am.* at 62-63.
[138] FDA, DOCKET NO. FDA-2014-N-0189, DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO THE FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT; REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF TOBACCO PRODUCTS AND REQUIRED WARNING STATEMENTS FOR TOBACCO PRODUCT PACKAGES AND ADVERTISEMENTS FINAL REGULATORY IMPACT ANALYSIS (2016), 62 [Hereinafter *Final Impact Assessment*].
[139] *Id.* at 63 (citations omitted).
[140] *See id.* at 61-65.
[141] *Id*. at 62 ("Reliable evidence on the impacts of warnings labels, premarket review, and marketing restrictions on users of . . . ENDS does not, to our knowledge, exist.").

3.3. California Regulations Relating to Textual Health Warnings

As noted above, nicotine is a chemical currently appearing in the Proposition 65 list.[142] Therefore, all electronic cigarette manufacturers must display an adequate Proposition 65 warning to consumers,[143] unless they determine that the levels at which nicotine is present in such products is such that they fall under Proposition 65's warning exemption.[144] Whenever applicable, the warning must comply with the requirement of California's Code of Regulations.[145] In general, a warning is compliant if it comports to the following format: "WARNING: This product can expose you to chemicals including [listed chemical], which is known to the State of California to [applicable identified harm, such as cause cancer]. For more information, go to www.P65Warnings.ca.gov."[146]

Some popular brands of electronic cigarettes, such as Juul and blu eCigs, display Proposition 65 disclaimers on their websites.[147]

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[142] Cal. Office of Env't Health and Hazard Assessment, Chemicals Known to the State to Cause Cancer or Reproductive Toxicity (Dec. 31, 2021), https://oehha.ca.gov/media/downloads/proposition-65//p65chemicalslistsinglelisttable2021p.pdf.

[143] CAL. HEALTH & SAFETY CODE § 25249.6.

[144] CAL. HEALTH & SAFETY CODE § 25249.10 provides the following three exemptions: "(a) An exposure for which federal law governs warning in a manner that preempts state authority. (b) An exposure that takes place less than twelve months subsequent to the listing of the chemical in question on the [Proposition 65] list. (c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity. . . .".

[145] Cal. Code Regs. tit. 27, § 25601.

[146] Cal. Code Regs. tit. 27, § 25601; *see* the sample warnings available at https://www.p65warnings.ca.gov/new-proposition-65-warnings.

[147] BLU, http://www.blu.com (last visited Feb. 1, 2022) (displaying a Proposition 65 warning at the bottom of the homepage); JUUL LABS INC., https://www.juul.com (last visited Feb. 1, 2022) (displaying a Proposition 65 warning at the bottom of the homepage).

4. Regulations Relating to the Promotion of Electronic Cigarettes

When the market was completely unregulated, manufacturers of electronic cigarettes had adopted several marketing tactics similar to those that successfully increased cigarette sales and usage in past decades. One such tactic was increasing advertising budgets to expand their communication channels.[148] That focus on advertising is explained by the fact that research shows that "[a]dvertisements impact adolescents' receptivity to and curiosity about tobacco products as well as increase risk for initiation and potential long-term use of nicotine."[149]

As part of that advertising, certain manufacturers' messaging seemed to promulgate the perception that electronic cigarettes were safe alternatives to regular tobacco products and potential smoking cessation devices.[150] That this was an advertising strategy pursued by electronic cigarette manufactures is supported by the findings of a meta study of studies conducted through June 2017 regarding electronic cigarette marketing, which found that "[a]n examination of commercially generated e-cigarette brand-sponsored social media and blog posts revealed that the majority of posts contained explicit and implicit smoking cessation claims."[151] The study also found evidence supporting that, as compared to traditional cigarettes, electronic cigarettes were presented in advertisements "as healthier,

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[148] Alexandra Bruell, *E-Cigarette Brands Spend More on Advertising and Keep Careful Watch on Health Claims*, ADAGE (Jan. 2, 2012), http://adage.com/article/news/e-cig-brands-marketing-spend-eye-health-claims/231863/.

[149] *E.g.*, Xiao Li et al., *National Trends of Adolescent Exposure to Tobacco Advertisements: 2012–2020*, PEDIATRICS, Dec. 1, 2021, at 46, https://publications.aap.org/pediatrics/article/148/6/e2021050495/183453/National-Trends-of-Adolescent-Exposure-to-Tobacco?searchresult=1%3fautologincheck%3dredirected.

[150] Toni Clarke, *U.S. Attorneys General Urge FDA to Regulate E-cigarettes*, REUTERS (Sept. 24, 2013), https://www.reuters.com/article/us-health-ecigarettes/u-s-attorneys-general-urge-fda-to-regulate-e-cigarettes-idUKBRE98N0ZK20130924.

[151] Lauren Collins et al., *E-Cigarette Marketing and Communication: How E-Cigarette Companies Market E-Cigarettes and the Public Engages with E-cigarette Information*, NICOTINE & TOBACCO RESEARCH, Jan. 1, 2019, at 15, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6610165/.

less expensive, more socially acceptable, unhindered by smoke-free policies, and more environmentally friendly."[152] Other meta studies have made similar findings.[153] However, both electronic cigarettes and traditional tobacco products are addictive.

In addition to traditional advertising, electronic cigarettes have sponsored events while promoting their brands, both before and after governmental regulations were enacted. For example, electronic cigarette company blu eCigs sponsored a music festival in 2013.[154] Another company, Juul Labs, sponsored the Jetsmarter Presents The Music in Film Summit at the high-profile 2018 Sundance Film Festival, in which renowned actors and singers participated.[155] On its part, the VUSE brand of electronic cigarettes sponsored McLaren Racing's car in the popular Indy500 Race in 2019.[156]

Those advertising efforts, in part, give context to the regulatory actions in the EU and the US, discussed below.

4.1. Regulations Relating to Health-Based Messaging

The aim of marketing communications for all products, including electronic cigarettes, is to secure sales. As discussed above, one way in which manufacturers' messaging may do so is by leading consumers to view electronic cigarettes as a safe alternative to traditional

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[152] *Id.*
[153] *See, e.g.*, Kahlia McCausland et al., *The Messages Presented in Electronic Cigarette–Related Social Media Promotions and Discussion: Scoping Review*, J. OF MEDICAL INTERNET RESEARCH, Feb. 5, 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6379814/.
[154] Press Release, blue eCigs, blu eCigs Announces Sponsorship of Sasquatch! Music Festival (May 20, 2013), https://www.prnewswire.com/news-releases/blu-ecigs-announces-sponsorship-of-sasquatch-music-festival-208127521.html.
[155] Chris Gardner & Ramona Saviss, *Sundance Film Festival 2018: Guide to Events, Parties and More*, HOLLYWOOD REPORTER (Jan. 16, 2018), https://www.hollywoodreporter.com/news/general-news/sundance-film-festival-2018-guide-events-parties-more-1073709/.
[156] SportsPro, *McLaren's IndyCar livery features Vuse e-cigarette branding* (Apr. 10, 2019), https://www.sportspromedia.com/news/mclaren-indycar-indy500-sponsorship-british-american-tobacco/.

tobacco products. However, the components of electronic cigarette vapor are not merely water,[157] as some may assume due to its similarity in appearance to steam. Carcinogens and other harmful substances may also present in the vapor.[158]

Separately, some consumers may view electronic cigarettes as providing health benefits in that they use them as a means to stop smoking traditional cigarettes. However, electronic cigarettes are not true cessation devices.[159] Although the public's perception concerning cessation benefits might be true to some extent, whether that benefit truly exists is unclear.[160] In that context, suggesting that electronic cigarettes are cessation devices may be misleading and poses several troubling problems. First, nicotine replacement therapy ("**NRT**") effectiveness studies usually measure rates of both smoking and nicotine addiction, while electronic cigarette studies suggesting a positive impact in cessation rates focus only on smoking.[161] Second, studies have not proven that electronic cigarettes are successful as cessation devices without posing health risks.[162] Third, some people might actually delay or avoid quitting smoking because they use electronic cigarettes as bridge

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[157] *E.g.*, Lucia Cancelada et al., *Heated Tobacco Products: Volatile Emissions and Their Predicted Impact on Indoor Air Quality*, ENV'T SCIENCE & SCIENCE & TECHNOLOGY, July 2019, https://escholarship.org/uc/item/5wf5t0k8; *E.g.*, Mohamadat Sleiman et al., *Emissions from Electronic Cigarettes: Key Parameters Affecting the Release of Harmful Chemicals*, 50 ENV'T SCIENCE & SCIENCE & TECHNOLOGY 9644 (2016), https://escholarship.org/uc/item/9s90850c.

[158] *Id*.

[159] *See* Library of the EU, *Briefing on Electronic Cigarettes*, *supra* note 92, at 3 (Cessation effectiveness are measured based of quit rates of both smoking and nicotine addiction, yet electronic cigarettes contain nicotine and foster addiction to that substance).

[160] *See, e.g.*, Richard J. Wang et al., *E-Cigarette Use and Adult Cigarette Smoking Cessation: A Meta-Analysis*, AMERICAN JOURNAL OF PUBLIC HEATH, vol. 111, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7811087/; CDC, *Adult Smoking Cessation—The Use of E-Cigarettes* (Jan. 23, 2020), https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html.

[161] Library of the EU, *Briefing on Electronic Cigarettes*, *supra* note 92, at 3.

[162] *See, e.g.*, Richard J. Wang et al., *E-Cigarette Use and Adult Cigarette Smoking Cessation: A Meta-Analysis*, AMERICAN JOURNAL OF PUBLIC HEATH, vol. 111, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7811087/; CDC, *Adult Smoking Cessation—The Use of E-Cigarettes* (Jan. 23, 2020), https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html.

devices to circumvent smoke-free zones. Considering electronic cigarettes' high levels of addictive nicotine content and its sustained use, there is no reason to believe that those devices would be as, let alone more, effective than tested NRTs in helping people quit smoking, if smoking is understood as the complete cessation of use of both tobacco *and* nicotine, as opposed to tobacco only.

The foregoing provides context regarding the impetus behind the relevant EU and US regulations concerning health-related messaging. It also gives an indication that relevant authorities must actively control for messaging that will likely mislead consumers into thinking that electronic cigarettes are safe to use because manufacturers have proven to be willing to resort to those messaging tactics to boost sales.

The following sections contain the EU and US regulations that apply to electronic cigarettes for which health-based marketing is used.

4.1.1. EU Regulations Relating to Health-Based Messaging

Under Article 20(1), the Tobacco Products Directive exempts from regulation electronic cigarettes that are otherwise regulated as medicinal products under the Medicinal Products Directive[163] or as medical devices under the Medical Devices Directive.[164] Research did not yield any examples of electronic cigarettes that are currently subject to regulation under

[163] Council Directive 2001/83, 2001 O.J. (L 311/67) (EC) [hereinafter *Medicinal Products Directive*]. Under Article 1(2) of the Medicinal Products Directive, a "medicinal product" means (i) "[a]ny substance or combination of substances presented for treating or preventing disease in human beings" and (ii) "[a]ny substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings. . . ."

[164] Council Directive 93/42, 1993 O.J. (L169) (EEC) [hereinafter *Medical Devices Directive*]. As relevant here, under Article 1(2) of the Medical Devices Directive, "medical device" means "any instrument, apparatus, [or] appliance . . . intended by the manufacturer to be used for human beings for the purpose of . . . prevention, . . . treatment or alleviation of disease. . . ."

either of the latter two Directives, particularly as a result of health-based claims or marketing.

4.1.2. US Federal Regulations Relating to Health-Based Messaging

As discussed above, electronic cigarettes that make modified risks claims or represent they are smoking cessation devices must apply for pre-market authorization from the FDA under the relevant approval tracks.[165] No electronic cigarette has obtained pre-market authorization as a smoking cessation device.

As part of the pre-market authorization process for modified risk products, the applicant bears the burden of meeting one of two standards. First, to obtain FDA approval, the applicant must provide sufficient scientific evidence to satisfy the FDA that, as used by consumers, such products will "(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."[166] This is a high standard of proof requirement, and no manufacture has been able to obtain pre-market authorization under this standard for an electronic cigarette product.

A second standard provides that "[w]hen the scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth" above, but "the scientific evidence that is available . . . demonstrates that a measurable and substantial

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[165] *See* 21 U.S.C. § 387k(a) (for modified risk products) and 21 U.S.C. § 387k(c) (for smoking-cessation products).
[166] 21 U.S.C. § 387k(g)(1).

reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies," then the FDA may provide pre-market authorization to products that are "appropriate to promote the public health" authorizing only "an explicit or implicit representation that such tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke. . . ."[167]

In July 2020, the FDA issued the first, and so far only, limited pre-market authorization under the second standard for an electronic cigarette product, covering the following modified risk claims, which the FDA determined would likely be proven to be correct in subsequent scientific studies:

"• The IQOS system heats tobacco but does not burn it.

• This significantly reduces the production of harmful and potentially harmful chemicals.

• Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."[168]

This regulatory approach is consistent with the goal of protecting public health in that it allows consumers to have access to products that are likely reduce negative health consequences, without the delay that would result if such access were granted only once health benefits are conclusively established. That is because scientifically establishing

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[167] *Id*.

[168] FDA, Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911(d) of the FD&C Act -Technical Project Lead, MR0000059- MR0000061,MR0000133, July 7, 2020, https://www.fda.gov/media/139796/download.

those health benefits may require conducting long-term longitudinal studies, as acknowledged in the FDCA, that are not as feasible when the sample of users is small due to the product not being available in the market.

4.2. Prohibition of Sponsorship of Sporting and Entertainment Events

Sponsorships are "an important form of marketing because it allows tobacco companies to associate their name and brands with a desirable lifestyle image, [and] people's pastimes and passions. . . ."[169] In fact, research has suggested that "[v]iewers of tobacco-sponsored sporting events have more brand awareness, more favourable attitudes towards tobacco use and preferences for specific tobacco brands."[170] Therefore, enacting a sponsorship ban is important as part of a holistic regulatory regime aimed at protecting minors so that use of electronic cigarettes is not normalized through its association with positive activities, such as sports. This is especially true if the absence of such a ban would allow manufacturers to circumvent advertising bans that are otherwise applicable to protect minors (such as bans on TV ads).[171]

4.2.1. EU Regulations Relating to Sponsorship of Sporting and Entertainment Events

The Tobacco Products Directive, in its Recital 43, recognizes that the growing popularity of electronic cigarettes makes it imperative to harmonize to an extent the rules governing event sponsorship with respect to such products. Accordingly, Article 20(5)(d) of the Tobacco Products Directive prohibits "any form of public or private contribution to any

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[169] April Roeseler et al., *Tobacco Marketing in California and Implications for the Future*, TOBACCO CONTROL, Apr. 2020, at i121-i29, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2976534/pdf/tc031963.pdf.
[170] *Id*.
[171] *See id*.

event, activity or individual person with the aim or direct or indirect effect of promoting electronic cigarettes . . . involving or taking place in several Member States or otherwise having cross-border effects. . . .” That prohibition is, of course, broad enough to cover sporting and entertainment events, and it is in line with the provisions of Article 13 of the FCTC. But it also allows for the enforcement of Article 20 with respect to sponsorships of any other kind of events, which is a reasonable means of providing for authority that can be responsive to how electronic cigarette manufacturers, distributors and retailers may choose to promote their products in the future.

The sponsorship prohibition by its terms, however, does not apply to intra-Member State events that do not have cross-border effects. The merits of regulating sponsorships are not reasonably understood as being justified only with sponsorships that have cross-border aspects. Therefore, Member States should consider taking similar action to regulate all sponsorships occurring within their territory that are not otherwise covered by Article 20 of the Tobacco Products Directive.

4.2.2. US Federal Regulations Relating to Sponsorship of Sporting and Entertainment Events

Under the Final FDA Tobacco Rules, entities that manufacture, distribute or retail tobacco products are prohibited from sponsoring sporting events in any manner that makes the sponsor recognizable in connection with a brand of *cigarettes or smoking tobacco*.[172] In other words, in contrast to the EU, the FDA chose to exclude electronic cigarettes from the sponsorship prohibitions when it promulgated the FDA Tobacco Rules in 2016. This is at odds with the intent to protect the youth from the use of electronic cigarettes because some

[172] 21 C.F.R. § 1140.34(c).

courts have already explicitly recognized that tobacco-related advertising and event sponsorship has a significant-enough effect on the consumer behavior of minors to serve as a substantial governmental interest on which government regulation may be based.[173] In fact, in *Disc. Tobacco*, the US Court of Appeals for the Sixth Circuit held that the restriction on event sponsorship met the applicable test concerning the First Amendment of the US Constitution test and was, therefore, validly enacted.[174]

The foregoing upholding of the sponsorship restriction could have served —and may still serve— as a foundation for the expansion of the restriction to electronic cigarettes, given the rates at which minors are purchasing and consuming such products.

4.2.3. California Regulations Relating to Sponsorship of Sporting and Entertainment Events

There are currently no California regulations concerning the sponsorship of events by electronic cigarettes manufacturers, distributors or retailers. As shown in different sections of this thesis, however, California has been proactive in matching (and often exceeding) the regulatory efforts of the US federal government concerning such products. Therefore, this is an area concerning which California's government may consider acting in the future in order to close the gap left open by the FDA Tobacco Rules as discussed above.

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[173] *See, e.g.*, *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 539-41, 542-43 (6th Cir. 2012).
[174] *Id.*

5. Regulations Relating to the Sale of Electronic Cigarettes

A combination of regulatory measures has been enacted in an effort to limit access to tobacco-related products, including electronic cigarettes. Those measures, applied to varying strictness degrees by the governments addressed in this thesis, include minimum purchase ages to curtail children's access to electronic cigarettes is to limit sales to people over 18 years old. While the EU does not currently regulate minimum purchase age for electronic cigarettes, the US and California have regulations in that area. To further that minimum-age requirement, some jurisdictions have implemented regulations concerning self-service, distance and Internet sales. Comparatively, the bulk of regulatory action concerning those types of sales has happened in the US, not in EU, as discussed in the following sections.

5.1. Minimum Age of Purchase Regulations

One of the most straightforward manners in which to regulate to protect minors from exposure to electronic cigarettes is to establish minimum purchase ages. It must be observed that the concept of adulthood (both from a social and legal perspective) varies country by country. Therefore, it is difficult to prescribe the age at which people may be given access to electronic cigarettes. Having said that, EU countries have by and large set the relevant age at 18 years old, with some nuances discussed below. Differently, as discussed below, the US federal and California governments have set the relevant age at 21 years old, even though legal majority is generally attained at 18 years old.

Ultimately, based on the data regarding the health risks posed by nicotine consumption discussed above, it appears that the US approach is more in line with the science because there is evidence suggesting that nicotine's deleterious effects on the brain can be

significant through age 25.[175] There is thus support for setting a minimum age at least that high, or at least as close to it as possible.

5.1.1. EU Regulations Relating to Minimum Age of Purchase

The Tobacco Products Directive does not contain provisions regulating the minimum age of purchase of tobacco or tobacco-related products, such as electronic cigarettes. And no other EU legislation regulating such sales were identified. Therefore, regulating the minimum age of purchase for electronic cigarettes is entirely within the purview of legislation at the Member State level.

Perhaps the reason there is an absence of EU-level legislation in this area is that 25 of the EU's 27 Member States have national laws limiting the sale of tobacco products to people who are 18 or older.[176] The minimum age in the other two countries, Belgium and Austria, is 16.[177] However, it appears that not all Member States have laws concerning the minimum age of tobacco *consumption*, and those that do enforce minimum consumption ages may do so depending on the location in which the smoking occurs (*e.g.*, it may be illegal for a 16-year-old to smoke in a public space but not in private).[178]

The foregoing highlights several opportunities to consider EU-level action, all of which have been taken to some extent in the US. First, the EU should consider ensuring that the minimum purchase age for tobacco products is applicable to modern nicotine-containing

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[175] US Surgeon General, *Surgeon General's Advisory on E-cigarette Use Among Youth*, https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf (last visited Jan. 30, 2022).
[176] EU Agency for Fundamental Rights, *Purchasing and Consuming Tobacco*, https://fra.europa.eu/en/publication/2017/mapping-minimum-age-requirements-concerning-rights-child-eu/purchasing-and-consuming-tobacco (last visited Feb. 5, 2022).
[177] *Id.*
[178] *See id.*

products, such as electronic cigarettes. Second, the EU should consider establishing a minimum consumption and furnishing age that matches the purchase age. This would close a loophole whereby it may be illegal to sell the product to a minor, but not illegal for an adult to purchase the product and furnish it to a minor. This has the potential of curtailing minors' access to tobacco-related products, including electronic cigarettes, as adults become unwilling to make such purchases in violation of the law.

Finally, third, the EU should consider increasing the minimum purchase age from 18 to 21. This undoubtedly creates tension between the concept of the legal age of majority (at which point children become adults who are legally entitled to make decisions for themselves) and a higher age threshold for consuming tobacco notwithstanding the consumers' adulthood. However, this may be justified on public health grounds because, as discussed above, nicotine's effects on the developing brain can be deleterious until age 25, as well as because it would allow delaying consumer exposure to carcinogenic substances for three years. In addition, this could further curtail minors' access to electronic cigarettes because, for example, 16-year-olds are more likely to have friends from school and their communities who are 18-year-olds rather than 21-year-olds who would also be willing to purchase electronic cigarettes for minors in violation of the law.

Exploring the legal mechanisms through which the EU may harmonize the minimum age for the purchase and consumption of tobacco products is beyond the scope of this thesis. However, if necessary to ensure a defensible legal basis for such harmonization, the EU may explore implementing an incentive mechanism that promotes voluntary Member State transposition, similar to the US federal mechanism discussed in the next section.

5.1.2. US Federal Regulations Relating to Minimum Age of Purchase

In 2019, the federal government amended the FDA Act (and directed the FDA to amend its regulations as necessary) to increase the minimum purchase age for tobacco products, which includes electronic cigarettes, from 18 to 21.[179] In addition, as amended, FDA regulations will require that retailers verify the age of a purchaser who does not appear to be at least 30 years old by means of a photographic ID that displays the purchaser's date of birth.[180] After that amendment, the minimum age for the purchase of tobacco products is aligned with the minimum purchase age of alcoholic beverages[181], which are also substances that may be harmful to minors if consumed excessively or irresponsibly. The FDA monitors compliance with those requirements and issues fines to violators,[182] the methodology of which has received court approval.[183]

Notwithstanding the foregoing, it is important to clarify what is meant when referring to minimum purchase ages introduced by US federal legislation. That is because it has long been settled that the US federal government is "one of enumerated powers."[184] In other words, the US federal government may take actions exclusively with regards to authority granted to it by the federal Constitution.[185] That authority does not include what is

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[179] Further Consolidated Appropriations Act, Pub. L. No. 116-94, § 603(a), 133 Stat. 3123 (2019); 21 U.S.C. § 387f(d)(5).
[180] Further Consolidated Appropriations Act, Pub. L. No. 116-94, § 603(b)(1), 133 Stat. 3123 (2019); 21 C.F.R. § 1140.14(b).
[181] 23 U.S.C. § 158.
[182] FDA, *Compliance and Enforcement*, http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm232109.htm (last visited Jan 30, 2022) (The FDA issues warning letters and levies monetary penalties for violations of minimum-age requirements. It also has searchable database of actions it took against violators.).
[183] *E.g.*, *Orton Motor, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 884 F.3d 1205, 1208 (D.C. Cir. 2018).
[184] *E.g.*, *McCulloch v. Maryland*, 17 U.S. 316, 405 (1819).
[185] *See, e.g.*, *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 534 (2012) ("The Federal Government is acknowledged by all to be one of enumerated powers. That is, rather than granting general authority to perform all the conceivable functions of government, the Constitution lists, or enumerates, the Federal Government's powers.") (internal quotations and citations omitted).

sometimes referred to as general police powers.[186] Therefore, the US federal government does not have authority to directly establish minimum purchase ages for products, such as electronic cigarettes.

However, the federal government may in effect enact such police-power-related requirements by enacting such a law and then stimulating its adoption by the states by making certain laws that provide funds to the states applicable to some extent only to states that have adopted the provisions of specific federal police-power-related laws. One of the clearest examples of that mechanism at work concerns the minimum drinking age because it operates pursuant to a single law, which provides for withholding "[8] per centum of the amount required to be apportioned to any State under [several laws] on the first day of each fiscal year . . . in which the purchase or public possession in such State of any alcoholic beverage by a person who is less than twenty-one years of age is lawful."[187]

That federal mechanism is, therefore, similar to an extent to the EU directive mechanism in that both mechanisms set standards that generally must be transposed into local law (*i.e.*, national or state law) to become effective. The major difference being, of course, that US states' transposition of the relevant federal law is voluntary, while Member State transposition of EU directives is mandatory. As discussed above, this voluntary incentive mechanism could be explored by the EU in order to harmonize tobacco purchase and

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[186] *See, e.g.*, *U.S. v. Lopez*, 514 U.S. 549, 566 (1995) ("The Constitution . . . withhold[s] from Congress a plenary police power that would authorize enactment of every type of legislation.") (citations omitted).
[187] 23 U.S.C. § 158(a)(1)(A)-(B); The mechanism at work with respect to the minimum purchase age of tobacco products is similar, but more complex enough to not represent the most appropriate example for this thesis. Additional understanding on this topic specific to tobacco products may be obtained through the resources available on the following federal government website: https://www.samhsa.gov/synar/about-synar.

consumption ages, especially if the minimum age is to be set at 21 as opposed to the now-common 18.

5.1.3. California Regulations Relating to Minimum Age of Purchase

California's Stop Tobacco Access to Kids Enforcement Act amended California's Business and Professions Code to enact restrictions on the sale of tobacco to minors. Importantly, the Business and Professions Code establishes 21 as the general minimum age of purchase for tobacco products.[188] That restriction applies to the sale of electronic cigarettes, which are explicitly covered by the Business and Professions Code's definition of tobacco products.[189] Selling tobacco products in contravention of the minimum-age requirement may result in the imposition of civil penalties, as well as in the suspension of the seller's license to sell tobacco products.[190] In addition, such violations may result in criminal prosecution for a misdemeanor[191] including for sales made by a merchant in person, but also through vending machines.[192]

5.2. Self-Service Sales

As discussed above, one of the main ways in which electronic cigarettes can be kept from the hands of the youth is to limit their sale to adults. In service of that aim, it is important to limit sales by any means that do not provide for the verification of a purchaser's age. Unsupervised self-service sales, such as through the use of vending machines, present such an issue. To address that, the federal US and California government have enacted

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[188] CAL. BUS. & PROF. CODE § 22958(a)(1). The Business and Professions Code provides an exception whereby people 18 or older who are active-duty members of the US armed forces may purchase tobacco products if they present their military ID as proof of age. CAL. BUS. & PROF. CODE § 22958(a)(2).
[189] CAL. BUS. & PROF. CODE § 22950.5(d)(1).
[190] CAL. BUS. & PROF. CODE § 22958(a)(1), (b)-(i).
[191] CAL. PENAL CODE § 308(a)(1)(A)(i).
[192] CAL. PENAL CODE § 308(a)(1)(D).

regulations limiting the locales in which vending machines for tobacco-related products, including electronic cigarettes, may be located. Differently, the EU does not appear to have enacted such regulations.

5.2.1. EU Regulations Relating to Self-Service Sales

The Tobacco Products Directive does not contain provisions regulating the sale of electronic cigarettes through self-service means, such as through vending machines. And no other EU legislation regulating such sales were identified. Therefore, regulating self-service sales of electronic cigarettes is entirely within the purview of legislation at the Member State level.

5.2.2. US Federal Regulations Relating to Self-Service Sales

With respect to sales of tobacco products, including electronic cigarettes, through means of electronic or mechanical devices, the US federal government prohibits such sales "except in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time."[193] The imposition of such a requirement at the state level is incentivized through the voluntary compliance mechanism discussed above. In practice, such vending machines are thus likelier to be limited to locations to which entrance is limited in consideration of other legal requirements pertaining to their main line of business, such as bars that deny entry to people under 21 to ensure compliance with minimum drinking age requirements.

[193] 21 C.F.R. § 1140.14(b)(3).

5.2.3. California Regulations Relating to Self-Service Sales

Under the Busines & Professions Code, California makes it unlawful to sell tobacco products, including electronic cigarettes, through vending machines, with one exception.[194] Namely, such products may be sold through vending machines located 15 feet or more away from the entrance of "public premises" that have been issued an "on-sale" license to sell alcoholic beverages.[195] Those quoted terms impart a significant restriction because they make the exception applicable generally only to alcohol-licensed establishments that do not serve food or that are authorized to sell food only incidentally to the purchase of alcoholic beverages.[196] In other words, for example, vending machines for the sale of electronic cigarettes may be located inside a bar, but not a restaurant.

This is an effective restriction because, in those permitted establishments, the presence of someone under 21 is generally prohibited and subject to misdemeanor charges against both the operator of the establishment and the under-21 individual.[197] Local jurisdictions are explicitly granted the authority to completely ban the sale of electronic cigarettes products by means of vending machines if they so desire.[198]

5.3. Distance and Online Sales

The relevant authorities should immediately consider adopting restrictions on the online sale of electronic cigarettes. Currently, there are no robust regulations on the part of the EU

[194] CAL. BUS. & PROF. CODE § 22960(a)-(b).
[195] CAL. BUS. & PROF. CODE § 22960(a)-(b).
[196] *See* CAL. BUS. & PROF. CODE § 23039.
[197] CAL. BUS. & PROF. CODE § 25665.
[198] CAL. BUS. & PROF. CODE § 22960(c).

of the US federal governments concerning distance and online sales of electronic cigarette, which means minors may not find it difficult to complete those types of purchases.

Ideally, online sales of electronic cigarettes should be banned to make it less convenient for consumers, especially minors, to purchase such products. Limiting access could then influence consumption rates, but the extent of such effect would need to be analyzed further due to the potential that such limitation may function more as an inconvenience rather than a deterrent with respect to nicotine-addicted persons. Alternatively, a more lenient approach would be for online retailers to require proof of age before shipping the products. The only acceptable proof of age should be a copy of a government-issued ID that shows that the buyer is at least 18 years old. Also, the name and address on that ID should match both the name and shipping address of the person receiving the products, as well as the name and billing address associated with form of payment used for the transaction.

5.3.1. EU Regulations Relating to Distance and Online Sales

Article 20 of the Tobacco Products Directive makes the cross-border distance sale of electronic cigarettes subject to the provisions of Article 18 of the Directive.[199] Under Article 18, Member States have the authority to prohibit cross-border distance sales into their territory.[200] Retailers in Member States that do not prohibit such sales are obligated to register themselves for such purposes in the Member State in which they are located and in the Member State in which their actual or potential customers are located.[201] The latter registration requirement is also applicable to retailers that are established outside the EU.[202]

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[199] Tobacco Products Directive, art. 20(6).
[200] Tobacco Products Directive, art. 18(1).
[201] *Id.*
[202] *Id.*

Importantly, retailers are required at the time of sale to verify that the purchaser meets the minimum age for purchase applicable in the Member State in which the purchaser is located.[203]

Those distance sales provisions suffer from two main deficiencies that may affect their effectiveness. First, Article 18 does not set forth the means through which retailers are required to verify a purchaser's age. Those details are, consequently, left up to Member States to regulate – if they regulate them at all. In the absence of adequate Member State regulation, it is possible that retailers may simply rely on an acknowledgement from the purchaser that he or she meets minimum age requirements without requiring further proof. A false age declaration by the purchaser would not entail any negative consequences, at least under the provisions of the Tobacco Products Directive. It is not difficult to imagine that minors desiring to purchase electronic cigarettes online might be willing to make such a consequence-free false declaration in order to obtain the products.

Second, there is a missed opportunity to verify the purchaser's identity at the time of delivery. Such a requirement may deter minors from using the identity information of adults in the household in order to make online purchasers of electronic cigarettes because the adult person identified as the recipient of the package would need to sign and identify himself or herself in order for the package to be released to them.

5.3.2. US Federal Regulations Relating to Distance and Online Sales

Neither the FDCA nor the FDA Tobacco Rules contain provisions regulating distance or Internet sales of electronic cigarettes. Therefore, those sales may take place under federal

[203] Tobacco Products Directive, art. 18(4).

law, provided that other applicable requirements are met (*e.g.*, observance of the minimum purchase age).

Relatedly, however, the Jenkins Act prohibits the US Postal Service[204] from accepting or delivering any package it knows, or has reasonable cause to believe, contains cigarettes or smokeless tobacco,[205] save for limited exceptions.[206] In December 2020, the Preventing Online Sales of E-Cigarettes to Children Act ("**POSECA**") was enacted to, among other things, amend the definition of "cigarette" under the Jenkins Act to include any "electronic nicotine delivery system."[207] In other words, POSECA made electronic cigarettes subject to the general non-mailability designation that was previously only applicable to traditional cigarettes under the Jenkins Act. POSECA also required the US Postal Service to promulgate final rules to regulate the application of that new designation imposed on electronic cigarettes.[208]

In October 2021, the US Postal Service promulgated those required final rules, making the Jenkins Act restrictions fully applicable to electronic cigarettes, as well as making unavailable the exception for mailing products for consumer testing purposes.[209] Major

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[204] The US Postal Service is an independent executive establishment of the US federal executive branch, which is tasked with the monopoly of the carriage of letters and packages to individual and commercial mailboxes. *See* Postal Reorganization Act, 39 U.S.C. §§ 101 *et seq*. Non-carriage services to mailboxes may be provided by private companies in the US, such as FedEx and UPS.
[205] 18 U.S.C. § 1716E(a)(1).
[206] 18 U.S.C. § 1716E(b). Of those exceptions, only two are relevant for direct-to-consumer sales: (i) intrastate mailing within the State of Alaska or the State of Hawaii, which are the only two noncontiguous states in the US (18 U.S.C. § 1716E(b)(2)), and (ii) products mailed to adults for purposes of consumer testing (18 U.S.C. § 1716E(b)(5)).
[207] 15 U.S.C. § 375(2)(A)(ii)(II).
[208] Consolidated Appropriations Act, Pub. L. No. 116-260, § 603, 134 Stat. 3137 (2020).
[209] Treatment of E-Cigarettes in the Mail, 86 FR 58398-01.

private carriers have also prohibited the mailing of electronic cigarettes using their services, including FedEx[210] and UPS.[211]

5.3.3. California Regulations Relating to Distance and Online Sales

California's Stop Tobacco Access to Kids Enforcement Act amended the Business and Professions Code to regulate distance sale of tobacco products, including electronic cigarettes.[212] As amended, the Business and Professions Code prohibits both direct or indirect sales or distribution of electronic cigarettes to persons who are not at least 21 years old using any public or private mail or package delivery service.[213] In service of that requirement, sellers and distributors of electronic cigarettes must verify that a purchaser of electronic cigarettes is 21 years old at the time of purchase by (i) checking the information provided by the purchaser against a database of government or (ii) if the previous verification fails or is not available, by obtaining an affidavit from the purchaser representing he or she is 21 years or older and a copy of a government-issued ID card.[214] In addition, the individual delivering the products must verify that the recipient is, in fact, at least 21 years old by requiring a signature and proof of identity in connection with delivering the package.[215]

Those California restrictions, particularly when read together with Jenkins Act restrictions, serve to curtail the online sale of electronic cigarettes to minors because products ordered online must be delivered only by the limited private couriers who allow mailing electronic

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[210] FedEx, *Tobacco*, https://www.fedex.com/en-us/shipping/guidelines-for-shipping-tobacco.html (last visited Feb. 1, 2022).
[211] UPS, *How to Ship Tobacco*, https://www.ups.com/us/en/support/shipping-support/shipping-special-care-regulated-items/prohibited-items/tobacco.page (last visited Feb. 1, 2022).
[212] CAL. BUS. & PROF. CODE § 22963.
[213] CAL. BUS. & PROF. CODE § 22963(a).
[214] CAL. BUS. & PROF. CODE § 22963(b)(1).
[215] CAL. BUS. & PROF. CODE § 22963(b)(5).

cigarettes and are able to comply with the identity verification requirements of the Business and Professions Code. Selling electronic cigarettes in contravention of the Business and Professions Code's provisions may subject the violator to civil penalties.[216]

[216] CAL. BUS. & PROF. CODE § 22963(f).

6. Regulations Relating to the Taxation of Electronic Cigarettes

At a basic level, government are justified in introducing taxation regimes for tobacco-related products in that such regimes may serve to take into account the social costs of tobacco use. But turning specifically to the youth, although the price elasticity of tobacco products varies by country and is generally inelastic, the consumption rates of young consumers is more elastic (i.e., more responsive to increases in price).[217]

That tendency of tax-driven prices increase to decrease tobacco consumption has been observed by the World Health Organization, which has stated that "significantly increasing tobacco excise taxes and prices is the single most effective and cost-effective measure for reducing tobacco use."[218] Under WHO guidance, tobacco taxes are significantly high when they are equal to "at least 75% of the cost of these health-harming products."[219] After introducing, or increasing, taxes to meet WHO standards, several countries have recorded a marked decrease in the prevalence of tobacco use.[220]

To explain how that tax effect works, it is important to emphasize that excise taxation is widely understood as being the most effective tax policy in terms of increasing the prices

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[217] *E.g.*, WHO FCTC Secretariat*, Price Elasticity* (Oct. 2019), https://untobaccocontrol.org/kh/taxation/wp-content/uploads/sites/3/2019/10/KH_BackToBasics4_Price-Elasticities_October2019.pdf; Although only limited research was identified, data suggests that the demand for electronic cigarettes may also be relatively elastic. *See Jidong Huang et al.*, *The Impact of Price and Tobacco Control Policies on the Demand for Electronic Nicotine Delivery Systems*, TOBACCO CONTROL, Apr. 2014, iii41-47, https://tobaccocontrol.bmj.com/content/tobaccocontrol/23/suppl_3/iii41.full.pdf.
[218] WHO, *Raising Taxes on Tobacco*, https://www.who.int/activities/raising-taxes-on-tobacco (last visited Jan. 29, 2022).
[219] WHO, *Countries Share Examples of How Tobacco Tax Policies Create Win-Wins for Development, Health and Revenues*, https://www.who.int/news-room/feature-stories/detail/countries-share-examples-of-how-tobacco-tax-policies-create-win-wins-for-development-health-and-revenues (Apr. 12, 2021).
[220] *Id.*

payable by consumers of tobacco-related products and, consequently, leading to a reduction in the consumption of those products.[221] The principal types of excise taxes are:

- "specific – levied as a monetary value per quantity of the product being taxed (e.g. 1,000 cigarettes, pack of 20 sticks, kilogram of tobacco); and
- *ad valorem* – levied as a percentage of the value (e.g. retail price, or the producer/ex-factory price or the cost, insurance and freight [CIF] value) of the product being taxed".[222]

The decision concerning which type of excise tax to implement to ensure that tax regulation is effective depends, in large part, on the market structure of the industry being regulated.[223] The structure of the tobacco industry is largely either monopolistic or oligopolistic.[224] The market for tobacco and tobacco-related products (in which companies producing electronic cigarettes operate) is oligopolistic in both the United States and the EU, as it is dominated not by a single firm but by a small group of large firms.

In an oligopolistic market, specific taxation tends to lead sellers to raise their prices to cover the costs of specific taxation without affecting their profits, which, in turn, tends to lead to lower consumption levels.[225] The opposite result (*i.e.*, lowering prices to sustain a high level of demand) tends to be disfavored because sellers would bear the full burden of covering the costs of specific taxation (which does not vary based on product value) out of

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[221] WHO, *WHO Technical Manual on Tobacco Tax Policy and Administration*, 12 (2021), https://www.who.int/publications/i/item/9789240019188 [hereinafter *WHO Tobacco Tax Manual*].
[222] *Id.*
[223] *Id.* at 19.
[224] *Id.*
[225] *See id.* at 20.

an ever-decreasing revenue base.[226] However, in oligopolistic markets where manufacturers can increase prices based on product differentiation that enhances perceived quality in the eyes of consumers, specific taxation may actually create incentives for manufactures to engage in such differentiation to persuade customers to pay the higher after-tax prices.[227] Still, "[e]vidence suggests that the tax structures most likely to lead to higher prices are uniform specific excise tax structures or mixed systems that rely more on specific excises."[228]

In the case of electronic cigarettes, manufacturers may more easily engage in the kind of differentiation that may skew the expected results of the tax measures when, of course, marketing of products is not subject to regulation and when consumer-attracting features such as flavorings are allowed. This illustrates the importance of not only ensuring that tax regulation carefully considers the optimal types and levels of excise taxation, but also how the chosen tax regime may be aided or hindered by other types of regulation applicable to electronic cigarettes.

Based on the above, it can be reasonably concluded that a mixed system of *ad valorem* and specific excise taxation would very likely reduce the number of overall users of tobacco-related products —particularly minors— in the EU and the United States.[229] But it must be considered that in response to higher tax-driven prices, consumers may resort to buying cheaper products from neighboring localities (*e.g.*, states or countries, as the case may be). Therefore, tax regimes applicable to electronic cigarettes are likely to be more effective when they are applied uniformly, either at the highest level of government (*e.g.*, at the

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[226] *See id.*
[227] *See id.* at 21-22.
[228] *Id.* at 25.
[229] *See* WHO Tobacco Tax Manual, *supra* note 222.

federal level in the US or through directives and regulations in the EU) or by local governments directly (*e.g.*, by US states or Member States in a way that results in no or negligible price difference from jurisdiction to jurisdiction).

6.1.1. EU Taxation of Electronic Cigarettes

The Tobacco Products Directive neither levies nor requires that Member States levy any form of excise taxes on electronic cigarettes.

The EU, however, in furtherance of ensuring the proper functioning of the Internal Market,[230] has enacted a mixed tax regime applicable to traditional cigarettes consisting of both *ad valorem* and specific taxes.[231] With some exceptions, Member States must ensure that the total excise duty levied (*i.e.*, *ad valorem* and specific taxes combined) in accordance with the Tobacco Taxation Directive equals "at least 60% of the weighted average retail selling price of cigarettes released for consumption."[232] That minimum taxation floor falls short of the 75% recommended by the WHO. But as of July 2021, 19 Member States exceeded the minimum 60% overall tax level, with the highest being approximately 70% in Estonia and Finland.[233] When taking into account VAT as part of the overall tax burden, however, all but four Member States meet the minimum tax level recommended by the WHO.[234] Therefore, at least from a theoretical perspective, the tax regime applicable to traditional cigarettes in accordance with the Tobacco Taxation Directive seems well-

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[230] Directive 2011/64/EU of the European Parliament and of the Council of 21 June 2011 on the Structure and Rates of Excise Duty Applied to Manufactured Tobacco, 2011 O.J. (L 176/24), Recital 3 [hereinafter *Tobacco Taxation Directive*].
[231] *Tobacco Taxation Directive*, arts. 7-14.
[232] *Tobacco Taxation Directive*, arts. 10-12.
[233] European Commission Directorate-General Taxation and Customs Union, *Excise Duty Tables Part III – Manufactured Tobacco* (July 1, 2021), https://ec.europa.eu/taxation_customs/system/files/2021-09/excise_duties-part_iii_tobacco_en.pdf.
[234] *See* Elke Asen, *Cigarette Taxes in Europe* (Sept. 2, 2021), https://taxfoundation.org/cigarette-tax-europe-2021/.

designed in that it comprises both *ad valorem* and specific taxes, and it generally yields high tax levels exceeding 60% (and 75% including VAT).

Based on the above, it appears prudent to recommend that the Tobacco Taxation Directive simply be amended to cover electronic cigarettes moving forward. However, a recent evaluation by the EU Commission of the effectiveness of the Tobacco Taxation Directive revealed several deficiencies. For example, the Tobacco Taxation Directive's overall positive effect "on public health has been moderate," and it "is not giving this stimulus any longer."[235] In addition, the high disparity in cigarettes' price notwithstanding the application of the Tobacco Taxation Directive results in making it easier for consumers, including the youth, to purchase cheaper cigarettes and leaving room open for the illegal trade in tobacco products.[236]

Thus, given the apparent need to amend the Tobacco Taxation Directive in a way that increases its effectiveness, the EU should take that opportunity to design a tax system applicable to electronic cigarettes that is responsive to price structures and consumer behaviors within the EU. This could also be accomplished in a separate directive, which could be justified based on the different physical characteristics and consumption patterns that exist between traditional cigarettes and electronic cigarettes. Either approach may be met with the support of Member States, which have in the past indicated "a strong

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[235] European Commission, *Executive Summary of the Evaluation of the Council Directive 2011/64/EU of 21 June 2011 on the Structure and Rates of Excise Duty Applied to Manufactured Tobacco* (Feb. 10, 2020), 1, https://ec.europa.eu/taxation_customs/system/files/2020-02/10-02-2020-tobacco-taxation-report-summary_en.pdf.
[236] *Id.*

preference for EU level harmonisation for the tax regime of e-cigarettes as different regimes prevent monitoring and control of cross border trade."[237]

6.1.2. US Federal Taxation of Electronic Cigarettes

The United States federal government does not levy any form of excise taxes on electronic cigarettes.

As one of the landmark legislations for his presidency, US President Biden has been lobbying for the passing of the Build Back Better Act. It would not be an understatement to describe the Build Back Better Act as being viewed by many in the US as controversial, largely due to its complex and broad spectrum of application. Still, a version of the Build Back Better Act was recently passed by the US House of Representatives on November 18, 2021.[238]

As relevant here, the Build Back Better Act contains a section that introduces a specific tax on nicotine products per 1,810 milligrams of nicotine, proportionally applicable to any fraction of nicotine thereof.[239] The applicable tax rate would be equal to the highest of (i) the tax rate applicable to small cigarettes under Section 5701(b)(1) of the Tax Code (currently $50.33)[240] and (ii) $50.33.[241] Previous House versions of the Build Back Better Act would have doubled the tax rate applicable to small cigarettes to $100.66.[242] Given that

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[237] European Commission, *Commission Staff Working Document Evaluation of the Council Directive 2011/64/EU of 21 June 2011 on the Structure and Rates of Excise Duty Applied to Manufactured Tobacco* (Feb. 10, 2020), 42, available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1570-Evaluation-of-the-excise-duties-applied-on-manufactured-tobacco_en.
[238] Build Back Better Act, H.R. 5376, 117th Cong. (as passed by the House, Nov. 18, 2021), available at https://www.congress.gov/bill/117th-congress/house-bill/5376/actions.
[239] Build Back Better Act §138520(a).
[240] 26 U.S.C. § 5701.
[241] Build Back Better Act §138520(a).
[242] H.R. 5376, 117th Cong. (as reported in the House, Sept. 27, 2021), available at https://www.congress.gov/bill/117th-congress/house-bill/5376/text.

the two possible Build Back Better Act tax rates applicable to nicotine would be the same under current law, the Build Back Better Act appears to have the aim of ensuring that nicotine is automatically taxed at a higher rate if the tax on small cigarettes is indeed increased in the future.

The above-mentioned tax regime suffers from two main deficiencies. First, it relies only on a specific tax. However, as discussed above, an ideal tax regime applicable to tobacco-related products consists of both specific and *ad valorem* taxes. Therefore, the inclusion of *ad valorem* taxes may be considered in order to improve the potential effectiveness of the Build Back Better Act's nicotine tax. Second, as the design of that nicotine tax tacitly recognizes, taxes on electronic cigarettes should be considered in light of the taxes applicable to other tobacco products that may be viewed as a substitute to electronic cigarettes due to pricing. In other words, the nicotine tax in the Build Back Better Act would likely benefit from the re-inclusion of increases in taxes of traditional cigarettes so that product-switching incentives are minimized.

Based on the foregoing, it would be prudent for the federal US government to ensure that the tax regime applicable to electronic cigarettes that is currently being considered by Congress is (i) designed in a manner that considers consumer behavior vis-à-vis tax regimes applicable to potentially substitute products (*e.g.*, cigarettes) and (ii) is composed of both *ad valorem* and specific taxes.

In addition to the foregoing, the federal government should consider whether federal law in the area of taxation of electronic cigarettes, or tobacco products in general, should preempt state law moving forward. As discussed in previous sections, the US federal government only possesses the powers granted to it by the Constitution, with the remainder

allocated exclusively to the states. But the US federal government "though limited in its powers, is supreme, and its laws, when made in pursuance of the Constitution, form the supreme law of the land."[243] Those federal Constitutional powers, within which the federal government may act and preempt state law, include the power to tax.[244] Therefore, based on US Supreme Court precedent, Congress has the authority to enact a comprehensive mixed tax regime applicable tobacco and tobacco-related products, including electronic cigarettes, that pre-empts state laws in this area.

In that respect, it is important to acknowledge that revenues from taxation of tobacco products represent a source of revenue. Therefore, state governments are likely to resist such a federal preemption proposal in Congress by voting against it. But if such preemption is pursued, revenue generated by that federal tax could then be divided between the federal government and the states in a way that ensures that states do not lose a material portion of the revenues they would have otherwise raised by taxing such products under state law. An added benefit of such preemptive action by the federal government could be that, because of uniform taxation in the entirety of the US, national consumption rates of tobacco-related products, including electronic cigarettes, may decline more quickly and in a more sustained manner than when different state tax schemes are not effective enough to incentivize residents to stop buying such products. That state-to-state discrepancy in tax regimes is, of course, likely to have an impact on nationwide statistics and tax-effectiveness studies. That discrepancy may also negatively impact the consumption rates of states that do have

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[243] *McCulloch* at 406.

[244] U.S. Const. art. I, § 8; *see Aloha Airlines, Inc. v. Dir. of Tax'n of Hawaii*, 464 U.S. 7, 12 (1983) ("[W]hen a federal statute unambiguously forbids the States to impose a particular kind of tax on an industry affecting interstate commerce, courts need not look beyond the plain language of the federal statute to determine whether a state statute that imposes such a tax is preempted.").

effective tax regimes, but whose residents resort to buying cheaper electronic cigarettes products sold in other states either in person or online.

Regardless of any tax-sharing arrangements, it must be acknowledged that states may challenge federal preemption of tobacco-related taxes in court. The expected costs and public debate such challenges may cause may make this proposal unrealistic from a political perspective notwithstanding the fact that setting uniform taxes at the federal level in accordance with WHO standards may be effective from a public health perspective.

Finally, if the efforts to enact a tax regime specific to electronic cigarettes as currently contemplated by the Build Back Better Act fail, then the federal government may consider broadening the application of existing tobacco taxes to cover electronic cigarettes. This approach could be a first step to later enacting taxes specific to electronic cigarettes, similar to the two-step process that occurred in California as discussed in the following section.

6.1.3. California Taxation of Electronic Cigarettes

The State of California has taken decisive steps in recent years to address the consumption rates of electronic cigarettes in the state. Originally, California's tax regime applied only to traditional tobacco products. But in 2016 the electors of California approved a proposition that subjected electronic cigarettes to *ad valorem* distribution taxes. And in 2021, the state government enacted a law that subjects electronic cigarettes to specific sales taxes. Those measures are discussed in detail in the following two sections.

Although no research was found analyzing what percentage those taxes represent with respect to total cost of electronic cigarettes, the tax regime is at least in line with the WHO recommendation of subjecting tobacco products to both *ad valorem* and specific taxation.

6.1.3.1 California Proposition 56 of 2016[245]

In the general election of November 2016, California electors approved a pro, known as Proposition 56, which resulted in the enaction of the California Healthcare, Research and Prevention Tobacco Tax Act of 2016.[246] Proposition 56 made two significant changes to state taxation of tobacco-related products.

First, Proposition 56 introduced an additional tax on the distribution of cigarettes[247] and, as relevant here, introduced the imposition of California's first cigarette-equivalent tax on the distribution of electronic cigarettes.[248] The California Department of Tax and Fee Administration is tasked with adopting the necessary regulations to effectuate the levy and collection of the tax on electronic cigarettes.[249]

Second, Proposition 56 revised the definition of "tobacco products" in the Revenue and Taxation Code to include "a product containing, made, or derived from tobacco **or nicotine** that is intended for human consumption. . . . Tobacco products shall also include electronic cigarettes."[250] This definitional change acted to bring electronic cigarettes under the coverage of the tax regime applicable to tobacco products, including the pre-existing distribution taxes levied in accordance with the Proposition 99 (The Tobacco Tax and Health Protection Act of 1988, approved in the general election of November 1988)[251] and

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[245] Cal. Sec'y of State, Official Voter Information Guide (2016), 10, 46-53, 134-141, https://vig.cdn.sos.ca.gov/2016/general/en/pdf/complete-vig.pdf.
[246] Cal. Rev. & Tax. Code §§ 30130.50-30130.59.
[247] Cal. Rev. & Tax. Code § 30130.51(a).
[248] Cal. Rev. & Tax. Code § 30130.51(b).
[249] Cal. Rev. & Tax. Code § 30130.51(b) (naming the "Board" as the right entity); Cal. Rev. & Tax. Code, gen. provision 20 (defining "Board").
[250] *See* Cal. Sec'y of State, Official Voter Information Guide, *supra* note 246, at 135; Cal. Rev. & Tax. Code § 30121(b).
[251] Cal. Proposition 99: Cigarette and Tobacco Tax Benefit Fund Initiative Constitutional Amendment and Statute (1988), available at https://repository.uchastings.edu/ca_ballot_props/980/.

Proposition 10 (The California Families and Children Act of 1998, approved in the general election of November 1998).[252] Consistent with the provisions of Proposition 99 and Proposition 10, under the Cigarettes and Tobacco Products Tax Law, distributors of tobacco products are subject to paying a distribution tax based on the wholesale cost of those tobacco products.[253]

The Legislative Analyst's Office ("**LAO**"),[254] as part of its analysis of Proposition 56, expressed an expectation that contemplated an increase in taxation applicable to cigarettes and other tobacco products would result in lower consumptions of those products, including electronic cigarettes, although it was unclear to what extent.[255] In general, this expectation is reasonable and generally bears out to be true, given that the literature reveals that an increase in price can be generally expected to result in a decrease in demand.[256] In addition, the LAO estimated that such increase in taxation would raise "between $1.3 billion and $1.6 billion in additional state revenue" in fiscal year 2017-2018 (the first full year of effectiveness), with the increase related to including electronic cigarettes in the definition of tobacco products likely generating "additional revenue . . . in the tens of millions of dollars annually".[257] Ultimately, that original revenue range proved to be correct, as actual 2017-2018 Proposition 56 revenues were approximately $1.5 million.[258] Subsequently,

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[252] Cal. Proposition 10: State and County Early Childhood Development Programs. Additional Tobacco Surtax. (1998), available at https://repository.uchastings.edu/ca_ballot_props/1162/.
[253] Cal. Rev. & Tax. Code § 30123.
[254] The Legislative Analyst's Office is a non-partisan office of the California Legislature, which, as relevant here, "estimates the fiscal effect on state and local government of all proposed initiatives (prior to circulation) and prepares analyses of all measures that qualify for the statewide ballot." Legislative Analyst's Office, *About Our Office*, https://lao.ca.gov/About (last visited Feb. 10, 2022).
[255] Legislative Analyst's Office, *Cigarette Tax to Fund Healthcare, Tobacco Use Prevention, Research, and Law Enforcement. Initiative Constitutional Amendment and Statute* (July 18, 2016), https://lao.ca.gov/ballot/2016/Prop56-110816.pdf.
[256] *See id.*
[257] *Id.*
[258] CAL. DEPT. OF TAX AND FEE ADMIN., Proposition 56 Summary of Revenues and Expenditure California Healthcare, Research and Prevention Tobacco Tax Act of 2016 Fund,

Proposition 56 revenues declined by 5% in fiscal year 2018-2019 to approximately $1.4M and by a further 4% in fiscal year 2019-2021 to approximately $1.3 million.[259] Interestingly, Proposition 56 revenues for fiscal year 2020-2021 were practically the same as those for 2020.[260]

Based on the previous discussion of tax effects on prices, it is reasonable to expect that the costs associated with Proposition 56 taxes were passed on directly to consumers. In other words, consumers who desired to purchase cigarettes and tobacco products after Proposition 56 became effective faced higher retail prices at points of sale because the distributors and resellers did not absorb the associated increase in costs. Therefore, because retail prices increased, the reduction in revenues can be associated with a reduction in sales volume, as opposed to a reduction in sales prices where sales volume remained constant. In that sense, Proposition 56 seems to have achieved the objective of reducing the consumption of cigarettes and tobacco products to some degree, at least as suggested by the decrease in Proposition 56 revenues in the fiscal years ending in 2018 through 2020.

Studies would need to be conducted to determine the reason for the apparent stabilization of Proposition 56 revenues in fiscal tear 2020-2021 as compared to the previous fiscal year. Having said that, there are at least two possible reasons that would not undermine the regulatory rationale underpinning Proposition 56. First, it is possible that consumer spending habits temporarily changed during the Corona pandemic, resulting in people who would have otherwise ceased using cigarettes and tobacco products delaying that decision. In this case, 2021 data is not comparable with data from previous years, and Proposition 56

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https://www.cdtfa.ca.gov/formspubs/pub403.pdf https://www.cdtfa.ca.gov/taxes-and-fees/prop-56-summary-rev-and-exp.htm.

[259] *Id.*

[260] *Id.*

may continue helping to further reduce the number of consumers of those products in the future.

Second, it is possible that enough time has passed after Proposition 56 was enacted such that the demand curve for cigarettes and tobacco products is or is close to being stable. That is, there might now exist an equilibrium between the prices of those products and the number of consumers willing to buy at those prices. In this case, Proposition 56 may be close to achieving the maximum effect on consumer behavior it can achieve by design.

Separately, it is also possible that, being *ad valorem*, Proposition 56 taxes no longer yield the level needed to sustain or increase the rate of product consumption (as suggested by a continuingly decreasing level of revenue generated). That is, perhaps a decrease in the value based on which the taxes are levied resulted in lowering prices for enough products to stop the trend of decreased consumption. An analysis into this factor may be justified based on what the consumption and revenue numbers are in future years, which would elucidate whether Proposition 56 taxes should be increased to further their effectiveness.

6.1.3.2 California Senate Bill 395 of 2021

As discussed above, taxation is an effective means of reducing the consumption of products in general, as well as of tobacco-related products. As also discussed above, however, after the approval of Proposition 56, electronic cigarettes were largely taxed in the same way as traditional tobacco products and, to some extent, cigarettes. In other words, there were no taxes specifically aimed at reducing the consumption of electronic cigarettes. This changed

with the enactment of California Senate Bill 395 ("**SB 395**") in October 2021,[261] which will become effective in July 2022.

In relevant part, SB 395 enacted the Healthy Outcomes and Prevention Education (HOPE) Act, which amended the Revenue and Tax Code to implement California's first excise tax that is applicable specifically to electronic cigarettes.[262] The SB 395 tax requires consumers to pay an excise tax equal to 12.5% of the sales price of such products purchased from a retailer for use in California.[263] Brick-and-mortar retailers will be obligated to specially set out the amount of the excise tax in any price marketing on signs posted inside or outside their establishments.[264] In addition, all retailers will be obligated to provide receipts to consumers who purchase electronic cigarettes, specially setting out the amount of excise tax paid.[265] Calling consumers' attention to the fact that they are paying an excise tax of such high magnitude when purchasing electronic cigarettes may bolster the tax's intended deterrent effect as compared to if retailers could simply increase product prices without highlighting the excise tax.

Although, as discussed, the increase in product prices caused by an increase in taxation can be expected to result in reduced consumption of those products, it is critical to determine whether tax-related regulatory actions are, in fact, yielding that intended results. To that end, SB 395 requires the California Department of Tax and Fee Administration to produce a report no later than July 1, 2024, analyzing the effect of the excise tax on retail purchases

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[261] Cal. S.B. No. 395, California 2021-2022 Regular Session, available at https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220SB395.
[262] *Id.*
[263] CAL. REV. & TAX. CODE § 31002(a)(1)(A).
[264] CAL. REV. & TAX. CODE § 31002(b).
[265] CAL. REV. & TAX. CODE § 31003 (The charge must be identified as the "California Electronic Cigarette Excise Tax").

of electronic cigarettes.[266] At minimum, the report must include a comparison between an estimate of total product purchase compared to total purchase prices in the years 2022 and 2023, respectively.[267]

California's direct experience regarding the successful deterrent effect generated by Proposition 56 regarding purchases of cigarettes and tobacco products, including electronic cigarettes, suggests that the new tax introduced by SB 395 may similarly dissuade at least some consumers from purchasing electronic cigarettes. Notably, the Assembly Committee on Revenue and Taxation estimates that the revenue generated by the tax introduced by SB 395 will equal "$32 million in 2022 (a half-year effect) and $66 million in 2023 (General Fund and special funds)."[268] As expected, taxation of electronic cigarettes are not generally thought to yield high revenues, as compared to total revenue generated by taxes on cigarettes and other tobacco products.[269]

But the estimated 2022 revenue (if annualized to $64 million) would be almost the same as the estimated 2023 revenue. This does not comport to the immediate year-to-year decrease in revenue generated by Proposition 56, which, in turn, would suggest an immediate decrease in consumption of covered products. That discrepancy in a downward trend on revenue generated by Proposition 56 and lack thereof concerning SB 395 may be due to several factors, one of which being that the demand for electronic cigarettes is more price inelastic than that of cigarettes and tobacco products. If consumption levels of electronic

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[266] CAL. REV. & TAX. CODE § 31008(a).
[267] CAL. REV. & TAX. CODE § 31008(b).
[268] Cal. Assemb. Comm. on Rev. and Tax., *SB 395 (Caballero) – As Amended May 3, 2021* (June 21, 2021), available at https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=202120220SB395.
[269] *See* CAL. DEPT. OF TAX AND FEE ADMIN., Proposition 56 Summary of Revenues and Expenditure California Healthcare, Research and Prevention Tobacco Tax Act of 2016 Fund, https://www.cdtfa.ca.gov/formspubs/pub403.pdf https://www.cdtfa.ca.gov/taxes-and-fees/prop-56-summary-rev-and-exp.htm.

cigarettes do not ultimately decrease significantly as a result of the SB 395 tax, then that regulatory action may well be a failure and, therefore, unjustified.

The upcoming SB 395-specific report will be instructive for purposes of explaining that revenue-decrease discrepancy, as well as analyzing the price sensitivity of electronic cigarette consumers. The insights generated from the report may aid California in determining how to effectively design any further action concerning taxation that is specific to those products. They may also serve as guideposts for other state governments' decisions on whether and to what extent the retail purchase of electronic cigarettes should be taxed at retail to decrease their consumption.

7. Conclusion

As demonstrated, governmental efforts in the EU, US and California to regulate electronic cigarettes have now spanned more than a decade. In large part, the health effects of electronic cigarettes are still not fully understood because, unlike traditional tobacco products, electronic cigarettes have not been in the market long enough to have allowed for the conduction of a plethora of long-term longitudinal studies.

Notwithstanding the foregoing, studies have shown that the youth in the relevant jurisdictions have been using electronic cigarettes in considerable numbers. Because they contain nicotine, electronic cigarettes present a health risk to those users, who face several well-known deleterious consequences such as a developmental brain and cognitive issues. In addition, electronic cigarettes use by young consumers may server as a gateway to later transitioning to the use of traditional tobacco products, which pose even more serious health consequences both from the perspective of an individual consumer and public health at a national level.

In large part to address those concerns, the relevant governments have enacted a patchwork of regulations. This thesis focused on identifying and discussing key regulatory actions concerning the ingredients in, warnings affixed to, and promotion, sale and taxation of, electronic cigarettes. Several conclusions may be drawn from the data presented, which are discussed next.

First, and perhaps paradoxically, the EU and the US federal government are aligned with respect to a lack of regulation concerning two topics that have been demonstrated to have the most potential for decreasing youth demand of electronic cigarettes. One such area is the use of flavorings, which are a popular feature attracting youth users to purchase

electronic cigarettes, as they did before for traditional tobacco products. Yet neither the EU nor the US governments have enacted regulations concerning the use of flavorings in electronic cigarettes. That is true even though both governments have enacted analogous bans applicable to traditional cigarettes whose parameters could have been simply expanded to apply to electronic cigarettes. It is not clear that leaving flavorings-related legislation to local governments in light of the foregoing may be reasonably justified.

Nevertheless, local governments may, in fact, choose to take such actions if they are aligned with their overarching regulatory priorities. That is the case in California, where the state government took steps to ban the sale of flavored electronic cigarettes by passing SB 793. However, facing the likelihood of losing a lawsuit challenging SB 793, industry actors took aim at the measure through the use of a referendum, as provided for under the state's constitution. It is not clear whether the referendum, set for November 2022, will succeed in repealing SB 793. But those repeal efforts shed some light on how important manufacturers view flavorings to be to their sales strategies. Those efforts also showcase that regulatory actions concerning flavorings bans are likely best taken at the national and supranational level, rather than placing every local jurisdiction in the position of having to battle industry actors in court or at the ballot to enact such a commonsense restriction.

Another such topic where there is both EU and US inaction concerns taxation. This is also paradoxical because taxation, particularly designed in accordance with WHO guidelines, has been demonstrated to be one of the most effective regulatory tools for generating a decrease in the consumption of tobacco products. However, this is another area in which the EU and the US governments have not taken meaningful regulatory action even though both governments have enacted tax regimes applicable to other tobacco products that they may broaden to apply to electronic cigarettes. Instead, regulatory actions were once again

left up to local jurisdictions. And, once again, California has taken such actions; first through its voters' enaction of *ad valorem* taxes in Proposition 56 and, second, through its government's enaction of specific taxes in SB 395. California's enactment of a mixed tax regime is line with WHO guidelines.

On the other hand, there are three topics concerning which all governments are aligned with respect to taking regulatory actions. First, both governments have enacted requirements that electronic cigarettes bear textual health warnings. This serves the purpose of providing consumers with information that would better allow them to make an informed decision concerning purchasing electronic cigarettes and, ideally, deter some consumers from making such purchases to avoid facing health risks. Second, both governments also contemplate that electronic cigarettes that are marketed in connection with health-based messaging may be regulated under the regimes that apply to medicinal products or medical devices. Research did not yield examples of electronic cigarettes being regulated under those special regimes. California regulations in this are do not exist due to federal law preemption of state-level tobacco standards laws. Third, all governments regulate distance sales either directly or indirectly with an aim to restrict minors' access to electronic cigarettes.

Separately, there two topics concerning which the EU stands as the sole regulator. First, and most importantly, only the EU has taken decisive action to establish parameters concerning both maximum levels of nicotine in electronic cigarette liquids and the consistency with which those devices deliver nicotine to consumers. Limiting the amount and delivery of nicotine serves public health purposes because it prevents accidental nicotine overdoses, for example. But it may also serve the purpose of affecting consumer behavior because it increases the number of devices and cartridges that users are forced to

buy to consume a satisfactory amount of nicotine, which may, in turn, serve as a deterrent to the use of those products. To establish the latter point, more specific research studies would need to be conducted.

In contrast, as noted, neither US federal law nor applicable regulatory rules set parameters concerning the use of nicotine in electronic cigarettes. Given that *the* main known addictive toxicant in electronic cigarettes is nicotine, it is not clear how that regulatory decision may be reasonably justified. In fact, in the absence of such regulation, high-nicotine electronic cigarettes may be obtained in the US market, in some cases containing as much nicotine as an entire pack of cigarettes. In light of that, neither of the two main beneficial purposes identified in the previous paragraph concerning nicotine regulation appears to be achievable in the US. California regulations in this are do not exist due to federal law preemption of state-level tobacco standards laws. As follow-up to this thesis, other writings may explore whether a state-level nicotine-based sales ban may be upheld as not constituting a tobacco standard, as is the case concerning flavorings bans.

Second, only the EU has enacted restrictions that would prohibit event sponsorships associated with electronic cigarettes, though those restrictions are limited to sponsorships with cross-border effects. Still, such a marketing limitation may aid the EU in its efforts to prevent the association of electronic cigarettes with otherwise positive activities, such as sports, and indirectly normalizing the use of those products.

Finally, with respect to the remaining regulations of the sale of electronic cigarettes, all regulatory action has occurred in the US. For example, the EU has not enacted a minimum purchase age for electronic cigarettes. In contrast, both the US federal and California governments have established 21 as the minimum age to purchase such products. This is a

straightforward restriction that directly serves the regulatory purpose of restricting the youth's access to electronic cigarettes and, consequently, protecting them from the harmful effect that result from nicotine addiction. Similarly, the EU has not enacted restrictions concerning self-service sales of electronic cigarettes, such as through vending machines. Differently, those restrictions exist in the US, where US federal and California law read together effectively operate to restrict those sales to locations in which only individuals who are 21 or older may be present, such as in bars.

Based on the foregoing, it is evident that the government of California has been the most active with respect to regulating electronic cigarettes. In fact, it has acted on all but one of the categories addressed in this thesis in which federal law is not understood to preempt state law. Differently, there is ample opportunity for the EU and US federal government to issue appropriate regulations, particularly with respect to two key areas that are known to absolutely affect the consumer behavior of the youth: banning the use of flavorings and enacting a tax regime composed of *ad valorem* and specific taxes in line with WHO guidelines. Based on the data presented, taking those two actions is likely to generate a positive effect respecting furthering the regulatory aim of protecting the youth from the harmful effects of nicotine addiction.

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