Chapter

Regulation of Electronic Cigarettes in the United States

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Abstract

In the United States, the manufacture, distribution and marketing of tobacco products is regulated by the US Food and Drug Administration (FDA), pursuant to authority extended to the agency in 2009 with the enactment of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). While that law initially gave FDA authority over certain categories of tobacco products (e.g., cigarettes, smokeless tobacco and roll-your-own tobacco), in August 2016, FDA's "Deeming Rule" extended that authority to all products that are made from or contain tobacco-derived substances, such as nicotine. Now, products such as cigars, pipe tobacco, shisha/hookah and electronic cigarettes (e-cigarettes) are subject to the Tobacco Control Act and FDA's authority. But regulators have struggled to keep up with the evolving technology and are still grappling with the public health consequences—both pro and con—and continue to adopt policies and regulations to address new issues that emerge (i.e., underage use and flavors).

Keywords: FDA, e-cigarette, tobacco, nicotine, Deeming, Tobacco Control Act, flavors, PMTA, premarket review, continuum of risk

1. Introduction

The emergence of less risky novel or "next generation" tobacco products such as e-cigarettes and heat-not-burn devices coincided with new regulatory authority provided to the US Food and Drug Administration (FDA), the health agency in charge of regulating the safety of consumer products such as food, drugs, medical devices, and cosmetics, under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which amended the existing Food, Drug, and Cosmetic Act (FDCA or Act). Pursuant to this new law, FDA now has the authority to regulate the manufacture, distribution, and marketing of tobacco products in the United States [1].

When it was signed into law in June 2009, the Tobacco Control Act provided FDA with immediate authority only over four categories of tobacco products, that is, cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco. Subsequently, in 2016, FDA finalized its "Deeming Rule," 81 Fed. Reg. 28974 (May 10, 2016), which deemed *all* products that meet the tobacco product definition (including, but not limited to, e-cigarettes, heat-not-burn, cigars, hookah/water-pipe, and pipe tobacco products) to be subject to its Tobacco Control Act authority. Now, newly deemed products are subject to a host of federal requirements including, among other things, premarket authorization for new products, ingredient

reporting, manufacturing establishment registration, harmful constituent testing, and sales and marketing restrictions.

Rising underage use of e-cigarettes has underscored the need for increased FDA enforcement of the Tobacco Control Act requirements, and has resulted in new policies aimed at restricted youth access to flavored e-cigarettes. This paper provides a comprehensive review of the regulatory requirements applicable to manufacturers and addresses how FDA's most recent policy announcements could impact the industry moving forward.

2. Overview of major Tobacco Control Act requirements

The Tobacco Control Act requires tobacco product manufacturers to, among other things, register their US manufacturing establishments with FDA, submit a list of US manufactured products, report the ingredients used in their products, submit certain health documents in their possession, test their products for specific harmful and potentially harmful constituents (HPHCs), include nicotine addiction warnings and certain other information on their labels and, most critically, obtain premarket authorization for any new products. Manufacturers are also subject to the adulteration and misbranding provision of the Act and are prohibited from making modified risk claims about their products without specific FDA authorization.

2.1 Marketing and sales restrictions

With respect to the sales and marketing of deemed products, FDA's Deeming Rule bans claims of reduced or "modified" risk and free samples to consumers, sets the minimum purchase age to 18 years, requires photo-ID verification at the point-of-sale, restricts vending machine sales of covered tobacco products to adult-only facilities, and requires nicotine addiction warnings on labels and advertising [2]. Furthermore, it is illegal to market or distribute any tobacco product whose packaging or labeling is misbranded under Section 903 of the FDCA, or deceptive and misleading under Section 5 of the Federal Trade Commission (FTC) Act.

2.2 US establishment registration and product listing

Section 905(b) of the Tobacco Control Act requires every person who owns or operates any establishment in the United States that manufactures, prepares, compounds, or processes finished tobacco products to register such establishment with FDA and submit a product list, which must be updated biannually (every December 31 and June 30) [3]. Foreign establishments are not presently required to register with FDA, but the agency has the authority to promulgate a regulation requiring them to do so. Here, the phrase "manufacture, preparation, compounding, or processing" includes repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product. US importers of tobacco products do not register with FDA unless they are also engaged in a manufacturing activity in the United States.

As noted, at the time of registration, registrants must submit to FDA a detailed list of all products that are being manufactured, prepared, compounded, or processed for commercial distribution in the United States, along with all labeling, and a representative sampling of advertisements. The term "commercial distribution" includes any distribution of a tobacco product to consumers or to another person for further manufacturing through sale or otherwise [4]. Registrants must also file a biannual report of certain changes to their product lists [5].

Registered establishments are subject to FDA inspection every 2 years [6]. FDA may inspect factories, warehouses, and other establishments in which tobacco products are manufactured, processed, packed, or held, as well as any vehicle being used to transport or hold such products [7].

2.3 Ingredient reporting

Section 904(a)(1)-(2) of the Tobacco Control Act requires that a manufacturer or importer submit a listing of all ingredients, as well as a description of the content, delivery, and form of nicotine in each tobacco product [8]. "Ingredients" here includes "tobacco, substances, compounds, and additives" [9]—that are added to any component or part of the products (e.g., to the tobacco, paper, filter, or other part). Products must be identified by brand and sub-brand and the ingredients by quantity in each brand and sub-brand. Manufacturers and importers are also required to submit information whenever any additive, or the quantity of any additive, is changed [10]. This requirement applies to all manufacturers no matter where they are located.

However, on April 13, 2018, FDA published a Revised Guidance for Industry which clarified that, at this time, FDA is effectively exempting e-cigarette device and hardware component/part manufacturers from the ingredient listing requirement [11]. Rather, FDA only intends to enforce the Section 904 ingredient listing requirement with respect to those tobacco products that are (1) made or derived from tobacco, or (2) made with *consumable* ingredients that are burned, aerosolized or ingested when the tobacco product is being used. Specifically, for e-cigarettes, FDA is now only seeking ingredient information on e-liquids, and **not** any hardware or components/parts such as:

- Electrical components including, but not limited to, batteries, charging systems, circuit boards, wiring, and connectors
- System software
- Digital display, lights, and buttons to adjust settings
- Connection adapters
- Cartomizers
- Coils
- Wicks
- Tanks
- Mouthpieces

2.4 Reporting health documents

Section 904 obligates tobacco product manufacturers and importers to submit certain health information to FDA. Specifically, manufacturers and importers are also required to submit all documents relating to the health, toxicological, behavioral, or physiologic effects of current or future tobacco products, constituents, ingredients, components, and additives (collectively, "Health Documents"). The

term "documents" is defined broadly and includes "writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations—stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form." At this time, however, FDA is only requesting health documents developed between June 23, 2009 and December 31, 2009. Companies that may not have been in business, or who were not producing health documents on their tobacco products at that time, are still required to notify FDA that they do not have any relevant health documents in their possession [12].

2.5 Harmful constituent testing

Section 904(a)(3) requires manufacturers and importers to report quantities of HPHCs found in tobacco products or tobacco smoke by brand and sub-brand. Out of more than 7000 such constituents, FDA has established a list of 93 HPHCs that tobacco companies will ultimately be required to report for every regulated tobacco product sold in the USA [13]. However, in recognition of current testing limitations for certain constituents on FDA's list, FDA has created representative or "abbreviated" lists of constituents for cigarettes, roll-your-own, and smokeless tobacco for which testing methods are well established and widely available [14].

With respect to e-cigarettes, as of the date of this writing, FDA has not provided any guidance or initiated rulemaking, so it is unclear whether HPHCs will need to be tested in the e-liquids themselves or in the vapor/aerosol formed when used in a device. In August 2016 FDA published a revised guidance document expanding the definition of HPHC to specifically include substances in the vapor (aerosol) produced by e-cigarettes. As defined by FDA in the guidance, an HPHC now includes any chemical or chemical compound in a tobacco product or in tobacco smoke that: (a) is, or potentially is, inhaled, ingested, or absorbed into the body, including as an aerosol (vapor) or any other emission; and (b) causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products" [14].

FDA is expected to issue formal guidance and regulations for the testing and reporting of HPHCs, ingredients, additives and other constituents pursuant to Section 915 [15].

2.6 Label requirements

The Deeming Rule extended a number of labeling requirements to deemed tobacco products. Specifically, by August 10, 2018, all deemed tobacco products must include the following on the labels of all products marketed in the United States:

- The name and place of business of the manufacturer, packer, or distributor;
- An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and
- The statement "Sale only allowed in the United States".

In addition, all nicotine-containing products must include the following warning on their labels "WARNING: This product contains nicotine. Nicotine is an addictive chemical" [16]. That warning label must comply with the specific requirements set forth in 21 C.F.R. § 1143.3(a). The nicotine addiction warning requirement, however, does not apply to products that are not sold with or contain

nicotine [17]. Rather, covered tobacco products that do not contain nicotine (i.e., zero-nicotine e-cigarettes that contain *another* tobacco-derived ingredient), must include the following statement on their label in lieu of the nicotine addiction warning: "This product is made from tobacco." Manufacturers of such products are further required to submit a statement to FDA certifying that the product does not contain nicotine.

2.7 Premarket authorization for new tobacco products

The Tobacco Control Act requires that FDA authorize the marketing of any new tobacco product through a lengthy and complicated application process. If a product was on the market as of February 15, 2007 it is considered "grandfathered" and exempt from FDA premarket review. If a tobacco product was introduced (or is intended to be introduced) after the February 15, 2007 "grandfather date," or if it was modified in any way after that date, it is a new product. Product modifications include, but are not limited to changes to a product's design, ingredients, components, parts, delivery mechanism, type of nicotine, etc. Changes to a product's labeling (including brand name, logos, colors, etc.), however, do not trigger the premarket review requirements [18].

The substantial equivalence (SE) report and the premarket tobacco application (PMTA) are the primary pathways for new tobacco product. The minor modification or SE exemption pathway is another option but only applies to changes in additives so is rarely utilized.

If a manufacturer can demonstrate, through the submission of an SE report, that its new product is substantially equivalent to a "predicate" product it may be authorized for sale. A "predicate" product is either a grandfathered tobacco product (that was on the market as of February 15, 2007), or tobacco product that, although not itself grandfathered, has been determined to be substantially equivalent to another grandfathered product. To demonstrate substantial equivalence, the manufacturer must provide evidence (such as data showing similarities in consumer perception, clinical data, abuse liability data, and toxicology) that the new product has the same (identical) "characteristics" as the predicate tobacco product or, if it has different characteristics, that the new product "does not raise different questions of public health." In other words, FDA may find a new tobacco product to be substantially equivalent to the identified predicate if the new characteristics do not create different public health concerns compared to the predicate. Public health concerns may include the potential to increase tobacco use initiation or decrease cessation.

For a PMTA, on the other hand, a predicate product is not needed. Rather, the manufacturer must demonstrate that the new product meets a very high public health standard. Specifically, it must be shown that the product, if made available in the United States, would be "appropriate for the protection of the public health." This requires assessing the product's potential impact on the population, including its impact on overall tobacco product cessation rates (i.e., the likelihood that people will stop using tobacco products), as well as initiation rates (i.e., the likelihood that people will start using tobacco products) [19].

To meet this high standard, FDA has recommended PMTAs include detailed scientific literature reviews, as well as numerous non-clinical, clinical (i.e., human), and long-term studies be performed, including, but not limited to, in-vitro and in-vivo (i.e., animal) toxicological studies (e.g., genotoxicity and cytotoxicity), as well as clinical and population-level studies to assess consumer perceptions, likelihood of initiation and cessation, product use patterns, abuse liability, and health outcomes [19].

2.7.1 Compliance policy for deemed tobacco products

As noted, in the final Deeming Rule FDA chose not to amend the February 15, 2007 grandfather date for deemed products, forcing *all* next generation products to go through pre-market authorization (because there are no known grandfathered e-cigarettes or heat-not-burn products). Moreover, as a result, the SE Report pathway (which, as noted above, requires a manufacturer to compare a new product to a predicate product) is unavailable, forcing all next generation products to go through the much more onerous and expensive PMTA.

FDA instead established a compliance policy that would allow any finished deemed tobacco product marketed after the grandfather date and prior to August 8, 2016 (the rule's effective date), to remain on the market for 2 years (without premarket authorization) until August 8, 2018, at which time PMTAs would need to be submitted. Products subject to such PMTAs that are accepted by FDA for review would be permitted to remain on the market for an additional year, until August 8, 2019 (the "sunset period"), at which point they would have to be removed from market and wait for FDA authorization (which, of course, is not guaranteed and could take years).

Lawsuits were filed challenging FDA's failure to change the grandfather date and the seemingly arbitrary 2-year PMTA compliance policy, and there has been an intense lobbying effort to get Congress to change the grandfather date—so far, to no avail [20].

However, on July 28, 2017, FDA announced a new "comprehensive regulatory plan to shift the trajectory of tobacco-related disease, death" that refocuses the agency's implementation of the Tobacco Control Act and the Deeming Rule [21]. While the focus of the announcement was to highlight the agency's long-term plan to potentially reduce nicotine in cigarettes to "non-addictive" levels, the agency also discussed the potential harm-reduction benefits of deemed products like e-cigarettes, and appeared to recognize that a "continuum of risk" of tobacco and nicotine-containing products exists.

In this regard, as part of its comprehensive policy announcement, FDA delayed the Deeming Rule's compliance policy deadlines to submit premarket authorization applications" (i.e., PMTAs or SE reports) for newly deemed tobacco products that were on the market on August 8, 2016. Under the new timelines, applications for previously marketed (but not grandfathered) combustible products, such as cigars, pipe tobacco and hookah tobacco, are now due by August 8, 2021, and applications for previously marketed non-combustibles, such as e-cigarettes, e-liquids and heat-not-burn products are due by August 8, 2022. FDA also indicated that it would be revising the sunset policy so that existing products under review can remain on the market pending review of their applications. New products intended to enter the market *after* August 8, 2016 must still obtain FDA marketing authorization *before* entering the market.

This new compliance policy delaying premarket review provided the industry, which was facing a de facto ban in 2018, much needed breathing room on the most complicated and expensive regulatory requirement. Critical to ensuring that such ban is not simply delayed until 2022 will depend, in part, on whether FDA provides more guidance and clarity on the PMTA process and requirements—particularly how to satisfy the population-level public health standard.

In addition to extending the premarket review deadlines for deemed products, FDA announced that it will publish advance notices of proposed rulemaking (ANPRMs) to seek (1) input on the potential public health benefits and possible adverse effects of lowering the level of nicotine in cigarettes to non-addictive levels, (2) public comments on the role of flavored tobacco products in terms of youth

initiation and harm reduction, and (3) scientific data related to the patterns of use and resulting public health impacts from premium cigars. FDA also indicated that it would develop product standards to address public health risks, such as, e-cigarette battery safety issues, and exposure to liquid nicotine by children, as well as examine ways to increase access and use of FDA-approved medicinal nicotine products intended to help smokers quit [21].

2.8 New FDA policy to address increase in underage e-cigarette use

In April 2018 FDA launched its Youth Tobacco Prevention Plan to address the sudden rise in underage use of certain types of e-cigarettes: pre-filled cartridge-based e-cigarettes sold mainly in convenience stores, gas stations and similar all-age retail outlets. FDA stated that between June and September 2018 nearly 1300 retailers across the country had received warning letters and/or monetary penalties for selling products to minors [22]. FDA also requested manufacturers of these popular cartridge-based e-cigarettes to submit proposals on how they plan to curtail the increasing youth-use of their products.

Subsequently, on November 15, 2018, FDA announced a new policy aimed at preventing youth access to flavored e-cigarettes [23]. First, FDA announced that all flavored e-cigarette products (other than tobacco, mint, and menthol flavors, or non-flavored products) will be required to be sold in age-restricted, in-person locations, or else potentially be subjected to a revised premarket review compliance policy deadline. This policy revision would apply to all e-cigarettes, including e-liquids, cartridge-based systems and cigalikes, in flavors except tobacco, mint, and menthol, sold in physical locations where people under age 18 are permitted. However, the new restrictions would not apply to e-cigarettes sold exclusively in age-restricted locations (e.g., a stand-alone tobacco retailer) that either prevent minors (individuals under age 18) from entering the facility at any time, or establish a walled-off adult-only section of the facility where flavored e-cigarettes can be viewed and purchased by persons 18 and older.

Second, FDA announced that it would seek to curtail the sale of flavored e-cigarettes (other than tobacco, mint and menthol) that are sold online without "heightened age verification" processes. To advance this goal, FDA plans to identify and publish a list of best practices for online retailers [23].

Third, FDA announced that flavored cigars will no longer be subject to the extended compliance date for premarket authorization (which currently sets the premarket application deadline for cigars on the market on August 8, 2016 to be August 8, 2021). However, this policy does not apply to the entire product category, as certain flavored cigars are considered "grandfathered" and exempt from premarket review if they were on the market as of February 15, 2007, as discussed above. To address this gap in regulatory authority, FDA plans to propose a product standard that would ban all flavored cigars [23].

Fourth, FDA announced plans to publish a Proposed Rule in the Federal Register that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars [23].

The Commissioner also noted that FDA plans to continue to aggressively pursue removing e-cigarettes marketed to children and/or appealing to youth from the market. These marketing practices may include "using popular children's cartoon or animated characters" or "names of products favored by kids like brands of candy or soda."

On March 13, 2019 FDA published a new draft guidance document entitled, *Modifications to Compliance Policy for Certain Deemed Tobacco Products* [24]. The draft guidance formalizes the November 2018 proposal from FDA discussed above, but

makes several changes. More specifically, the draft guidance eliminates the compliance policy for flavored e-cigarettes (other than tobacco, mint, menthol and unflavored products) sold or marketed in a manner that is (a) targeted to minors or likely to promote ENDS use by minors, or (b) offered for sale in ways that pose a greater risk of minor access. Such products will be subject to immediate enforcement.

In terms of targeting minors, the guidance states that FDA is evaluating how companies may utilize social media to market to minors, as well as radio and television (which are platforms that are prohibited for cigarette advertising). FDA further implied that products with labeling and/or advertising that use "youth appealing cartoons as well as the use of minors or people who appear to be minors in multimedia advertisements" could be the subject of enforcement. The draft guidance also identifies the following circumstances which pose a "greater risks of minor access":

1. Products sold in locations that minors are able to enter at any time (e.g., the entire establishment or an area within the establishment);

2. Products sold through retail establishments and online retail locations that have sold to minors—as indicated by FDA's searchable retailer inspection database—after issuance of the final guidance document;

3. Products sold online without a limit on the quantity of product that a customer may purchase within a given period of time; or

4. Products sold online without independent, third-party age-and identity-verification services that compare customer information against third-party data sources, such as public records.

The draft guidance also shortens the compliance policy by 1 year for all flavored ENDS (other than tobacco, mint, menthol and unflavored products), even if such products are marketed responsibly to adults. If the draft guidance is finalized, such flavored products on the market on August 8, 2016 will have until August 8, 2021 to submit PMTAs (which must be accepted by FDA for substantive review).

Finally, the guidance keeps in place, for the time being, the existing compliance policy for tobacco, mint, menthol and unflavored ENDS on the market as of August 8, 2016. Accordingly, these products still have until August 8, 2022 to submit premarket applications.

FDA indicated that the reason it is modifying the compliance policy for e-cigarettes in the manner described above is (i) "to encourage more prompt filing of premarket submissions for certain ENDS products"; (ii) "to focus the Agency's enforcement resources where there is a greater threat to public health"; and (iii) "to balance that public health threat against the potential benefit to providing adult smokers noncombustible options to allow them to completely switch from the use of combustible products."

While it is unclear how FDA will enforce the new compliance policy if it becomes effective, the draft guidance expressly places the onus on manufacturers to control distribution and sale of their products to retail customers by, among other things, "requiring terms, conditions, or controls in their contracts with downstream distributors (wholesalers, distributors, importers and/or retailers) to prevent youth access."

3. Conclusion

The e-cigarette industry has grown rapidly in the United States since the products were first introduced to the market in 2007. Regulators have struggled to keep up

with the evolving technology and are still grappling with the public health consequences—both pro and con. In the USA, the FDA's new authority over traditional tobacco products such as cigarettes was extended to cover e-cigarettes and other novel products. Now, newly deemed tobacco products are subject to the Tobacco Control Act requirements including, among other things, premarket authorization for new products, ingredient reporting, manufacturing establishment registration, harmful constituent testing, and sales and marketing restrictions. Regulators also continue to adopt policies and regulations to address new issues that emerge (i.e., underage use).

Manufacturers of flavored e-cigarettes should be most concerned with complying with FDA's recently revised premarket review compliance policy. In this regard, to potentially avoid being subject to immediate enforcement, and to remain eligible for the August 8, 2021 PMTA compliance date, manufacturers of flavored e-cigarettes must work with their retailers and distributors to ensure that their products are not sold in (1) all-age retailers (i.e., non-adult only facilities such as convenience stores and gas stations) that do not have separate walled-off section for flavored products, (2) online stores that do not have a limit on bulk purchases or third-party age and identity verification services, or (3) brick-and-mortar and online stores that have previously been cited for selling products to minors.

Manufacturers must further ensure that their products are not viewed as targeting or promoting use to minors. Companies should review their labeling, packaging, social media, websites, and advertising/marketing materials with the understanding that FDA could broadly argue that the use of certain flavors, descriptive flavor names, packaging and label colors, images of food, fruit, or desert, cartoon images or illustrations, playful characters, or young models, among other things, might trigger immediate enforcement under the modified compliance policy.

Finally, even if manufacturers can avoid immediate enforcement against their flavored e-cigarettes, the August 8, 2021 compliance date is fast approaching. It is critical that companies start working to prepare PMTAs sooner rather than later to have any chance of meeting that deadline.

Conflict of interest

Author Azim Chowdhury is a Partner at Keller and Heckman LLP in Washington, DC. In his law practice he represents tobacco and e-cigarettes companies in matters of regulatory compliance. He is also counsel to the Right to be Smoke-Free Coalition, a trade association of e-cigarette businesses that are challenging FDA's Deeming Rule in court.

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References

[1] Prior to the Tobacco Control Act, the Federal Trade Commission (FTC) had primary jurisdiction over the advertising and marketing of traditional tobacco products, such as cigarettes and smokeless tobacco

[2] Technically, the minimum purchase age, nicotine addiction warning and vending machine sale restriction only apply to deemed "covered" tobacco products, which is defined in the Deeming Rule to mean any tobacco product deemed to be subject to the Tobacco Control Act, but excludes any component or part that is not made or derived from tobacco. 21 C.F.R. § 1140.3. 2018

[3] A "finished" tobacco product is defined in the Deeming Rule as "a tobacco product, including all components and parts, sealed in final packaging intended for consumer use"

[4] FDA. Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments [Internet]. 2014. Available from: http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM191940.pdf [Accessed: December 10, 2018]

[5] Food, Drug, and Cosmetic Act, 21 U.S.C. § 905(i)(3)

[6] Food, Drug, and Cosmetic Act, 21 U.S.C. § 905(g)

[7] Food, Drug, and Cosmetic Act, 21 U.S.C. § 704

[8] Food, Drug, and Cosmetic Act, 21 U.S.C. § 904(a)(1)-(2)

[9] For purposes of this reporting requirement, an additive means "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical"

[10] Food, Drug, and Cosmetic Act, 21 U.S.C. § 904(a)(3)

[11] FDA. Guidance for Industry: Listing of Ingredients in Tobacco Products (Revised)* [Internet]. 2018. Available from: https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM527044.pdf [Accessed: December 10, 2018]

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[13] 77 Fed. Reg. 20,034 (April 3, 2012)

[14] FDA. Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act [Internet]. 2012. Available from: http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM297828.pdf [Accessed: December 10, 2018]

[15] Food, Drug, and Cosmetic Act, 21 U.S.C. § 915

[16] 21 C.F.R. § 1143.3(a) (2018)

[17] 81 Fed. Reg. 28979 (May 10, 2016)

[18] Phillip Morris USA Inc., et al. v. United States Food and Drug Administration, et al., 202 F. Supp. 3d, 31 (D.D.C. 2016)

[19] 21 U.S.C. § 387j(c) (2018)

[20] On July 21, 2017, the U.S. District Court for the District of Columbia ruled in the Nicopure Labs, LLC v. Food and Drug Administration lawsuit brought by the e-cigarette industry challenging aspects of the Deeming Rule. The court ruled entirely in favor of the FDA granting the agency's motion for summary judgment and holding that: (1) FDA acted within the scope of its statutory authority; namely, that it was legally permitted to e-cigarettes as tobacco products subject to regulation; (2) it was not arbitrary and capricious for the agency to subject e-cigarettes to premarket review and labeling requirements; (3) the new rules being applied to e-cigarettes do not violate the First or the Fifth Amendments to the Constitution; and (4) the agency was not required to undertake a formal cost-benefit analysis when promulgated the Deeming Rule. That decision has been appealed to the U.S. Court of Appeals for the District of Columbia Circuit

[21] FDA. FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death [Internet]. Available from: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm?utm_campaign=CTP%20News%3A%20NAS%20Report%20-%2012318&utm_medium=email&utm_source=Eloqua&elqTrackId=eee7ad075ae24d0b86dee239fd30bd01&elq=aa6a287fc5c44ef29e6f0e9b81140760&elqaid=2177&elqat=1&elqCampaignId=1520 [Accessed: December 10, 2018]

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