



HEATED CIGARETTES

How States Can Avoid Getting Burned



Heated cigarettes are garnering increased attention as commercial tobacco product manufacturers tout their marketing success abroad and begin introducing the products into the U.S. market.

Although the tobacco industry refers to them as “heat-not-burn” products, this term is a misnomer that attempts to downplay the harm of using these products. In fact, some heated cigarettes are lit by fire, and many product components have obvious signs of charring or discoloration after use, evidence that burning occurs. Moreover, there is no known independent research that demonstrates that these products present less harm to the user than conventional cigarettes. This fact sheet provides an overview of this category of products, describes products currently available on the U.S. market, and explains how heated cigarettes fit into a comprehensive regulatory scheme.



Overview of Heated Cigarettes

“Heated cigarettes” is a broad term that encompasses a range of products with two common elements:

- 1 Low Temperature Combustion.** Heated cigarettes are different from conventional cigarettes because they heat the tobacco to a lower temperature than conventional cigarettes, which generally maintain a temperature of 1250-1300°F.¹ According to industry descriptions of heated cigarettes, the products usually heat tobacco to a temperature between 450 - 700°F, and sometimes as low as 99°F.² This heating produces an aerosol that contains nicotine and other harmful chemicals.³
- 2 Processed Tobacco Leaf.** Heated cigarettes differ from e-cigarettes because they contain processed commercial tobacco leaf as the nicotine and/or flavor source in the product, not just nicotine extracted from commercial tobacco.

Potential Public Health Impacts of Heated Cigarettes

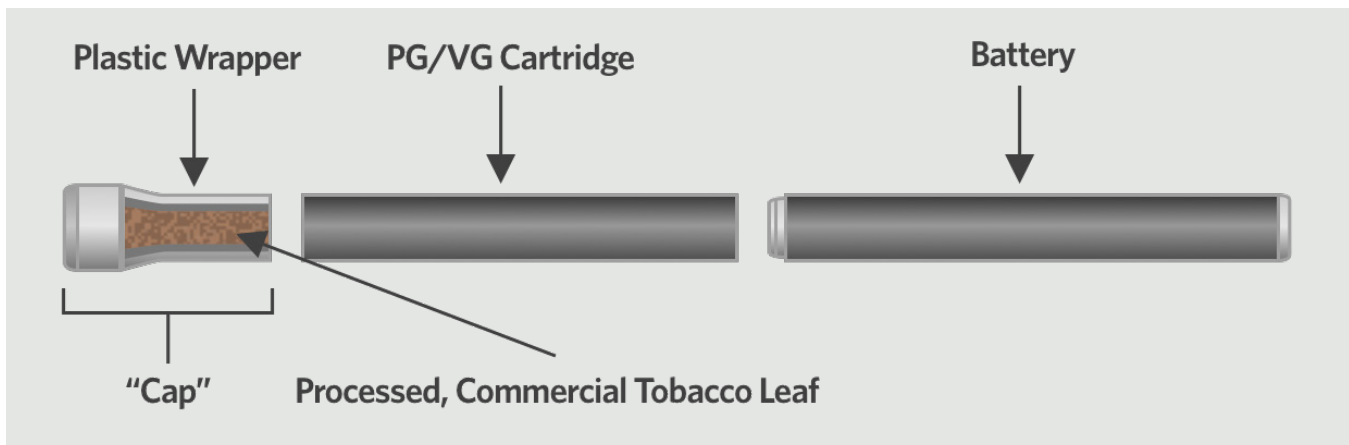
The act of processing the tobacco plant—for example, curing and storing the tobacco—produces many toxicants and carcinogens found in all commercial tobacco products. Contrary to industry claims, there is little evidence demonstrating that heated cigarettes are less harmful than conventional cigarettes. Problematically, the research that does exist has been conducted primarily with funding from the tobacco industry itself. At least one independent study conducted on iQOS revealed many of the same harmful and potentially harmful constituents in iQOS emissions compared to the control cigarettes.⁴

Current Landscape of the Heated Cigarette Market

Several types of heated cigarettes are currently available abroad and at least two types of heated cigarettes have already been introduced into the U.S. market. These products vary significantly in design and composition. Some resemble e-cigarettes and function in a similar manner, while others more closely resemble conventional cigarettes. The following summaries are based on current information, which is limited.

Currently available products:

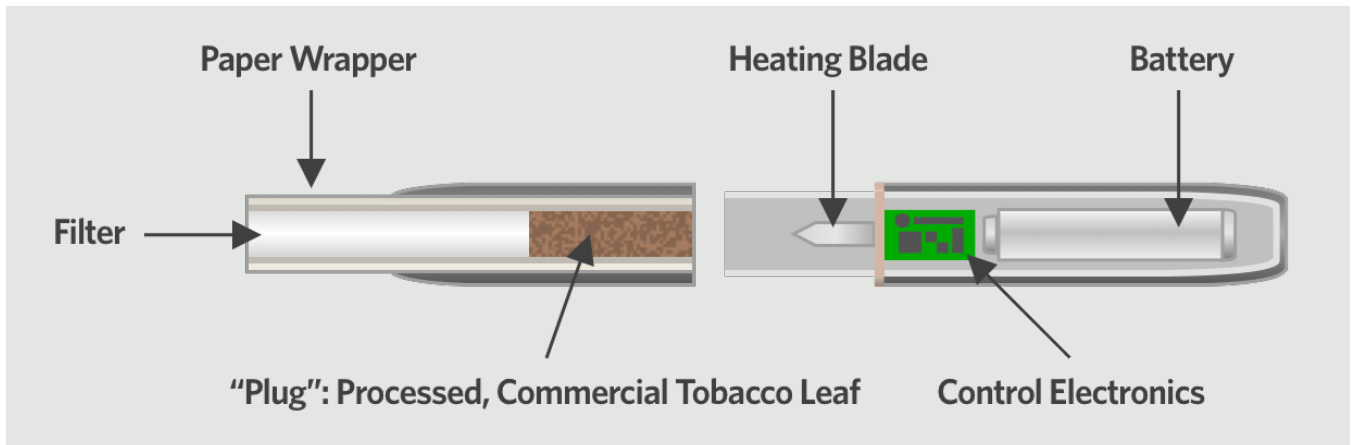
- **Japan Tobacco International's (JTI) Vapeleaf.** Vapeleaf includes a battery operated heating element, a propylene glycol/vegetable glycerin (pg/vg) liquid cartridge, and a granulated processed tobacco leaf "cap." The battery heats the cartridge, which produces an aerosol that is drawn through the tobacco leaf "cap" as the user inhales, extracting nicotine and flavor from the "cap." The manufacturer claims that the heating element reaches a maximum temperature of 99 °F. Vapeleaf was first introduced in 2017 to four states and has recently been expanded to two other states.⁵ It can be purchased online or through local retailers, and is available in regular (tobacco), menthol green, and menthol purple flavors. Importantly, this product was introduced into the U.S. market without premarket authorization from the FDA, as required by law.⁶



Japan Tobacco International's Logic Vapeleaf (PloomTech)

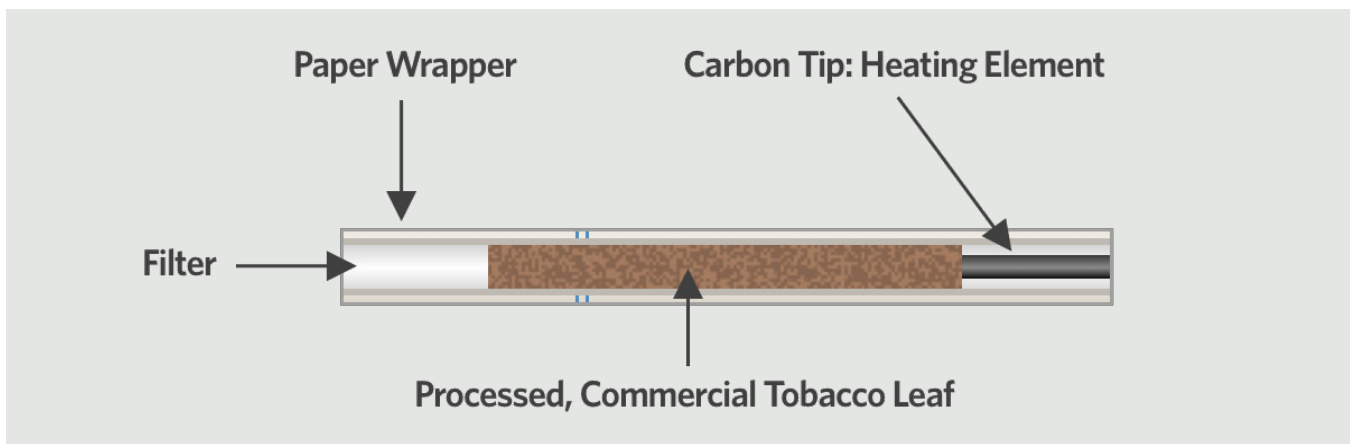
Possible future products:

- **Philip Morris International's (PMI) iQOS.** iQOS uses an electronic heating element to heat a "blade" that pierces the end of a "heat stick," inserted into the iQOS device. The "heat stick" looks similar to a conventional cigarette, but is shorter. Additional "heat sticks" can be purchased separately from the device and come in packs of twenty, just like conventional cigarettes. The "heat stick" is made of a processed tobacco leaf plug that includes glycerin, a filter, and a paper wrapper. The processed tobacco leaf is the source of the flavor and nicotine. This product is available in Japan, Switzerland, Korea, Israel, and a few other countries and PMI has filed a marketing application with the FDA.⁷



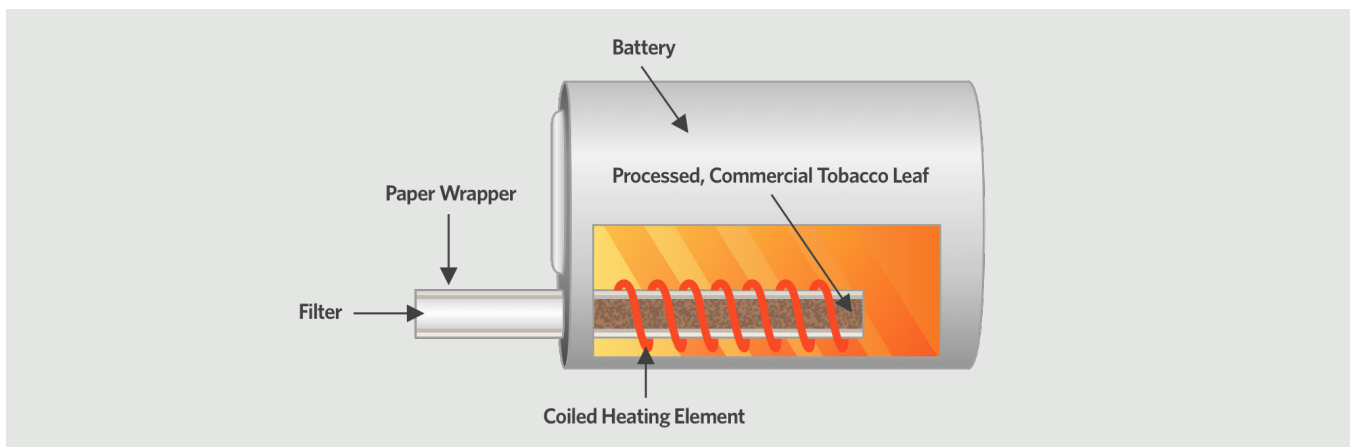
Philip Morris International's iQOS

- **British American Tobacco's (BAT) Neocore (previously R.J. Reynold's Eclipse and Revo).** Neocore does not use a battery-heating unit like many other heated cigarettes; instead, it uses a charcoal element at the tip of an otherwise conventional cigarette. The user employs a lighter or a match to light the charcoal tip, which in turn heats the tobacco leaf. The user inhales through a filter and obtains flavor and nicotine from the processed tobacco leaf.⁸ For a brief time in February 2014, Revo was sold in Wisconsin as an updated version of Eclipse, a heated cigarette introduced by R.J. Reynolds in the 1990s. After BAT acquired Reynolds in 2017, BAT filed a substantial equivalence report with the FDA to market its new version of the product, Neocore.⁹



British American Tobacco's Neocore

- **British American Tobacco's Glo.** Glo has a coiled heating system into which a "neostik" is inserted. Glo heats the processed tobacco leaf inside the "neostik" to produce an aerosol. The "neostik" looks similar to a conventional cigarette with tobacco leaf and a filter surrounded by paper. The processed tobacco leaf is the primary flavor and nicotine source. This product is available in Japan and news reports indicate that the company intends to apply for premarket authorization from the FDA in 2018.¹⁰



British American Tobacco's Glo

Federal Regulatory Landscape for Heated Cigarettes

Under the Family Smoking Prevention and Tobacco Control Act, the U.S. Food and Drug Administration requires premarket authorization of new tobacco products. In May 2016, the FDA announced a final rule "deeming" all products made or derived from tobacco products to be subject to the agency's authority. All newly deemed products that were already on the market on August 8, 2016 were allowed to remain on the market but need to apply for authorization no later than August 8, 2022. For any new products entering the market after August 8, 2016, manufacturers must seek authorization before selling the products in the U.S.¹¹ With the exception of Eclipse/Revo/Neocore, no heated cigarette products were on the market prior to that date. Products marketed without FDA authorization are potentially subject to an FDA enforcement action.

State and Local Regulatory Landscape for Heated Cigarettes

Regulation of tobacco products varies widely between states, but all states have laws that protect clean indoor air, prohibit sales to minors or those under the age of 21, and impose taxes on tobacco products. Because these laws generally address other common tobacco products like cigarettes as well as products like e-cigarettes, the question of whether heated cigarettes are also regulated hinges on how a jurisdiction defines the products that it regulates. In some states, heated cigarettes may already be incorporated into broad definitions for tobacco products, and in other states, they may not be covered in certain regulatory areas because of narrower definitions. Finally, there are also states in which the analysis is not entirely clear and whether or not the products are regulated in particular areas will depend on the interpretation of enforcement agencies and, potentially, the courts.

The Public Health Law Center's 50-state analysis of these three types of laws (<http://www.publichealthlawcenter.org/resources/us-heated-cigarette-regulations-50-state-review>) found several key terms and provisions that would be important to include in any comprehensive regulatory scheme that unambiguously captures heated cigarettes. While some state laws may already cover these new products, comprehensive regulation of heated cigarettes depends on evaluating and, if needed, updating current laws. The information below highlights some examples of issues that have been identified. Updating or drafting new laws to overcome these issues should not be undertaken without assistance from attorneys at the Public Health Law Center or a licensed attorney familiar with the laws of your jurisdiction.

Issues in Clean Indoor Air Laws

Clean indoor air laws generally operate by prohibiting "smoking" in certain areas (such as public buildings and workplaces). The restrictions' scope typically depends upon the definition of smoking. Heated cigarettes, in general, are touted to be "smoke-free," producing only a harmless vapor. Depending on how clean indoor air laws have been updated in response to other contemporary products, like e-cigarettes, the definition of "smoking" may or may not capture heated cigarettes. A handful of states have updated their comprehensive clean indoor air laws to include e-cigarettes and some have established separate laws restricting e-cigarette use.¹² Oftentimes, these separate laws do not restrict e-cigarette use at the same level as conventional combustible products.

Many definitions of smoking include undefined, ambiguous, or problematic terms. The two most common terms are "lighted" and "burning." Depending on the wording of the definition, some states and territories only need to find that the undefined term "lighted" applies to heated cigarettes, but other states and territories need to find that both the undefined terms "lighted" and "burning" apply in order for the use of heated cigarettes to be considered smoking.

The Meaning of “Burning”

No state or territory has a statutory definition for the term “burning” related to commercial tobacco products. From a scientific standpoint, burning is a chemical process that involves three main elements: oxygen, fuel, and heat that results in an irreversible chemical conversion.¹³ While “burning” in the smoke-free context has not been interpreted by courts with respect to heated cigarette use,¹⁴ there is an area of law that has given some guidance on how to interpret this term: arson. Courts have held that burning means any physical change, usually evidenced by charring or blackening, to the structure that was set on fire or was close enough to a heat source to be damaged and charred.¹⁵

Whether a heated cigarette product “burns” within the scientific or legal meaning is dependent on the specific product. Pictures and video of heated cigarettes after use show obvious charring on the paper of products that include a paper wrapper. However, some of the products heat tobacco at a temperature much lower than that needed for partial combustion. Ultimately, definitions that include “burning” as an operative term may include some products, especially products where a consumer uses a lighter or match to heat a carbon tip, and may not include products that are more like e-cigarettes.

The Meaning of “Lighted”

Another undefined and potentially problematic term is “lighted.” There are several dictionary definitions of the word lighted, and two are primarily relevant in this context: 1) “to set burning” or “ignite”—for example, lighting a match or a cigarette; and 2) “to turn or switch on,” for example, illuminating a dark room.¹⁶ No relevant case law apparently exists regarding the meaning of “lighted,” so other areas of law do not shape this analysis. Relying on the first dictionary definition, the term lighted would likely encompass carbon tip products. Other products that are more electronic in nature could be captured under the second definition of lighted. Without a clear definition of the term, however, it is impossible to say with certainty whether the term “lighted” would include the use of heated cigarettes.

Solutions in Drafting or Updating Definitions to Encompass Heated Cigarettes

Adding the terms “heated” and “activated” to definitions can help clarify that heated cigarettes are included in a law’s definition of smoking. Thus, for example, a definition that now covers “inhaling or carrying a lighted tobacco or other plant product” would be better drafted if it covered “inhaling or carrying a lighted, **heated, or activated** tobacco or other plant product.” Definitions that only cover “burning” tobacco products or only cover named types of tobacco products, such as cigarettes or cigars, could be expanded to cover all products made with

tobacco, nicotine, or other plants that are heated or activated. “Lighted” could be deleted in some definitions where it is made redundant by more specific terms. In the alternative, states could add a definition for the word “lighted” that includes both heating and activating, which would then require no direct change to the definition of “smoking.” As discussed above, carefully making these changes could make clear that heated cigarettes are covered by existing smoke-free prohibitions.

For example, edits to common definitions would produce language such as:

“‘Smoking’ means inhaling, exhaling, burning, or carrying any lighted, **heated, or activated** cigar, cigarette, or pipe, or any other lighted, **heated, or activated** tobacco, nicotine, or plant product intended for inhalation, including hookah and marijuana, whether natural or synthetic. ‘Smoking’ also includes the use of an electronic smoking device.”

“Smoking means the burning, **heating, or activating** of a **lighted** cigarette, cigar, pipe or any other substance containing tobacco or another plant.”

Issues in Laws Establishing a Minimum Legal Purchasing Age

Minimum legal purchasing age laws commonly include a prohibition on providing any tobacco products to those below the designated age. Because these laws are designed to prevent access to all tobacco products intended for consumption, heated cigarettes are usually covered. This means that the vast majority of states prohibit access to heated cigarettes for those under the legal purchasing age. Many states prohibit youth access to e-cigarettes by separately defining them as “alternative nicotine products” or “vapor products” and because of their similar functionality to e-cigarettes, heated cigarettes with electronic heating sources are often covered by these definitions. Because these laws primarily prohibit access to tobacco products, having multiple defined terms is not problematic as long as the prohibition is the same for all covered products. However, having a broad definition of tobacco products is the preferred approach for capturing both existing and emerging products. Before assuming that a state’s specific minimum legal purchasing age law or a local ordinance covers heated cigarettes, be sure that the language of the law prohibits the sale of heated cigarettes.

Issues in State Tax Codes

Tobacco tax laws usually operate by classifying or defining a group of products and determining the tax rate on those products in the form of an excise tax based on quantity, weight, or value. Currently, all states tax cigarettes and most states tax other classes of tobacco products, some making distinctions between types of products and others lumping all non-cigarette tobacco products into one category.

Due to some ambiguity in existing definitions, many state definitions could cover heated cigarettes as either “cigarettes” or another class of products. Because cigarettes are generally the product with the highest tax rate, taxing heated cigarettes at the same rate as conventional cigarettes would discourage the use of these products and advance public health efforts to address the harms posed by commercial tobacco products.

Many states define cigarettes as “any roll *for smoking* made wholly or in part of tobacco. . . .” Often the tax definition of “tobacco products” also requires that the products be “for smoking or chewing,” or use similar language. While many heated cigarettes have sticks that are made of processed tobacco leaf wrapped in some sort of roll, it is not clear if a tax authority would apply the undefined term “for smoking” to heated cigarettes.

Solutions in Drafting or Updating Definitions to Encompass Heated Cigarettes

Because the harm reduction benefits of heated cigarettes have not been established, jurisdictions could consider updating language to ensure that heated cigarettes are considered “cigarettes” for tax purposes. To do so, a jurisdiction can either eliminate the term “for smoking” or define it to ensure that it captures heated cigarettes.

One way to broaden the definition by excluding the term “for smoking” is to more closely mirror the federal tax definition for cigarettes. Importantly, proposed packaging for iQOS heat sticks and previous packaging for Neocore (when sold as Revo) reveal that those products are labeled as “Class A” cigarettes for taxation at the federal level. Amending tax codes to conform to federal standards is generally noncontroversial.



The federal definition of cigarette is:

(b) Cigarette.--“Cigarette” means--

(1) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and

(2) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1).¹⁷

For heated cigarettes that contain tobacco with a paper wrapper, federal taxation of these products as “cigarettes” seems assured. For heated cigarettes where the tobacco is contained in a plastic cap, it is possible that an enforcement authority could interpret the plastic container as wrapping the tobacco in “any substance not containing tobacco.” Jurisdictions could use the word “contained” rather than “wrapped” to clear up any lingering ambiguity.

Conclusion

When new tobacco products enter the market, important questions are raised regarding how those products can and should be regulated and heated cigarettes are no exception. Unlike e-cigarettes that were so different from existing products that they did not fit into existing regulatory schemes, heated cigarettes seem to be similar enough to other tobacco products that broad, comprehensive definitions can cover the new products. States and localities should analyze relevant laws to determine whether heated cigarettes are already covered and, if it is not clear, update or draft language to ensure that heated cigarettes are included in all tobacco regulations. Because there has been no demonstrated reduction in the health risks associated with heated cigarettes, the protection of public health requires that the sale and use of heated cigarettes be comprehensively regulated, preferably as strictly as cigarettes are regulated.

This publication was prepared by the Tobacco Control Legal Consortium, a program of the Public Health Law Center at Mitchell Hamline School of Law, St. Paul, Minnesota. The Public Health Law Center provides information and legal technical assistance on issues related to public health. The Center does not provide legal representation or advice. This document should not be considered legal advice.

This publication was supported by Cooperative Agreement Number 5 NU58DP006263-02-00, funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Department of Health and Human Services.

Endnotes

- 1 Conventional cigarettes reach a peak temperature of around 1500 °F and smolder around 1250 – 1300°F. Richard R. Baker, *Temperature Distribution Inside a Burning Cigarette*, 247 NATURE 405 (1974), <https://www.nature.com/articles/247405a0>.
- 2 Conventional cigarettes are often referred to as “combustible cigarettes,” which could be considered a misnomer from a scientific perspective. Complete combustion occurs at a temperature much higher than temperatures reached by conventional cigarettes (> 2370°F). In fact, a cigarette user is exposed to many toxicants as a result of incomplete combustion and the degradation from heating tobacco. U.S. DEP’T HEALTH AND HUMAN SERV., HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING-ATTRIBUTABLE DISEASE: A REPORT OF THE SURGEON GENERAL 37 (2010), <https://www.ncbi.nlm.nih.gov/books/NBK53014>.
- 3 The chemical composition of the aerosol generally includes nicotine, inorganic compounds (e.g. carbon monoxide), polycyclic aromatic hydrocarbons (e.g., benzene), and volatile organic compounds (e.g., formaldehyde). Grant O’Connell et al., *Heated Tobacco Products Create Side-Stream Emissions: Implications for Regulation*, J. ENVTL. ANALYTICAL CHEM. 1000163 (2015); Gideon St. Helen et al., *IQOS is Not a Reduced Exposure Product Yet* (2018) (unpublished manuscript) (on file with author); Reto Auer et al., *Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name*, 177 J. AM. MED. ASS’N INTERNAL MED. 1050 (2017); Noel Leigh et al., *Tobacco-Specific Nitrosamines in Heated Tobacco Product IQOS* (2018) (unpublished manuscript) (on file with author).
- 4 Gideon St. Helen et al., *IQOS is Not a Reduced Exposure Product Yet* (2018) (unpublished manuscript) (on file with author); Reto Auer et al., *Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name*, 177 J. AM. MED. ASS’N INTERNAL MED. 1050 (2017); Noel Leigh et al., *Tobacco-Specific Nitrosamines in Heated Tobacco Product IQOS* (2018) (unpublished manuscript) (on file with author).
- 5 Ian Jones, *Technical Features of Ploom Tech, JTI’s Novel Tobacco Vapor Device* (2018), <https://isontech.info/images/ISoN-Tech-PDF/3.%20JT%20International/JT%20International.pdf>.
- 6 Originally, Vapeleaf was only sold in four U.S. states; New York, Texas, New Jersey, and Florida. It recently expanded to Connecticut and Virginia. Logic, <https://logicvapes.us/e-cigs-vaping-devices/logic-vapeleaf> (last visited Aug. 2, 2018).
- 7 U.S. DEP’T HEALTH AND HUM. SERVS., Modified Risk Tobacco Product Applications, 82 Fed. Reg. 27487 (proposed June 15, 2017), <https://www.federalregister.gov/documents/2017/06/15/2017-12369/modified-risk-tobacco-product-applications-applications-for-iqos-system-with-marlboro-heatsticks>.
- 8 Reynolds Am., Transformation: Past, Present, Future (Nov. 17, 2014), http://files.shareholder.com/downloads/RAI/56475241x0x-794523/530E0B5A-09C1-4DEF-83A7-5F6182F79065/RAI_2014_Investor_Day_PDF.pdf.
- 9 Richard Craver, *Reynolds’ Tobaccoville Plant Could Get Boost from FDA Authorization of Company’s Latest Heat-not-burn Cigarette*, WINSTON-SALEM JOURNAL (July 26, 2018), https://www.journalnow.com/business/reynolds-tobaccoville-plant-could-get-boost-from-fda-authorization-of/article_afd376fc-90ca-11e8-8b89-57086961b4a3.html.
- 10 Angelica LaVito, *You May Soon See a Product That Heats Tobacco Instead of Burning It*, CNBC (Jan. 25, 2018), <https://www.cnbc.com/2018/01/24/philip-morris-heat-not-burn-tobacco-product-iqos-undergoes-review.html>.
- 11 Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143).
- 12 See, e.g., Tobacco Control Legal Consortium, U.S. E-Cigarette Regulations – 50-State Review (2018), <http://www.publichealthlawcenter.org/resources/us-e-cigarette-regulations-50-state-review>.
- 13 JAN REES, THAT’S CHEMISTRY! (2000) (ebook), <http://www.rsc.org/learn-chemistry/resource/res00001800/burning?cmpid=C-MP00005343#!cmpid=CMPO0005343>.
- 14 One case in New York found that a subway policy that defined “smoking” using the word “burning” did not apply to e-cigarettes, but this case does not address the new slate of products that are somewhere between e-cigarettes and traditional commercial cigarettes. *People v. Thomas*, slip op. 26033 (N.Y. Crim. Ct. Feb. 5, 2016).
- 15 See *People v. Haggerty*, 46 Cal. 354 (1873); *Benbow v. State*, 128 Ala. 1 (1900).
- 16 “light,” Dictionary.com (2018), <https://www.dictionary.com/browse/lighted?s=t> (last visited Aug. 2., 2018).
- 17 26 U.S.C. § 5702(b) (2018).