



## HEATED TOBACCO PRODUCTS: PHILIP MORRIS INTERNATIONAL'S IQOS

Philip Morris International's (PMI) IQOS and other heated tobacco products are among the latest iteration of tobacco products introduced by tobacco companies.

IQOS is currently marketed in at least 50 countries. Unlike in most other countries, PMI had to first obtain an order from the U.S. Food and Drug Administration (FDA) to market and sell IQOS in the United States. FDA authorized PMI to sell IQOS on April 30, 2019 and authorized IQOS as a "modified risk tobacco product" (MRTP), allowing the marketing of IQOS with specific reduced exposure claims (but denying reduced risk claims) on July 7, 2020. The IQOS MRTP order does not allow the product to be marketed as "safe" or even "safer," "FDA approved," or as presenting less risk of disease than other tobacco products. IQOS is currently being sold in three cities in the U.S.

### What are heated tobacco products?

While conventional cigarettes rely on the combustion of tobacco to create the inhaled smoke, heated tobacco products (HTPs), sometimes called "heat-not-burn" products by the tobacco industry, use an electronic device to heat a stick (or plug) of compressed tobacco and other chemicals to a high enough temperature to produce an inhalable aerosol, but below the temperature required for full combustion. The aerosol contains nicotine and varying amounts of other chemicals that can also be found in cigarette smoke.

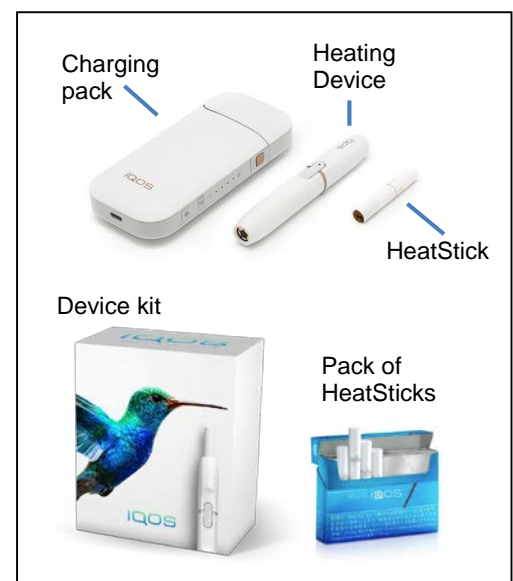
Heated tobacco products are not entirely new to the United States. In the late-1990s, Philip Morris test-marketed a product similar to IQOS called Accord, but it was not well-accepted by consumers and the company dropped it.<sup>1</sup> In the mid-1990s, Reynolds American marketed Eclipse, a cigarette with a charcoal tip that is lit with a lighter to heat the tobacco. Reynolds American test-marketed a similar product, Revo, in 2015, but ended sales of both products after minimal interest.<sup>2</sup> Now owned by British American Tobacco, Reynolds American received marketing orders from FDA to market a new version of Eclipse and Eclipse menthol,<sup>3</sup> but it does not appear the product is yet being sold.

Currently, most of the major transnational tobacco companies sell heated tobacco products in various countries: British American Tobacco (parent company of Reynolds American, Inc.) markets glo, Japan Tobacco International sells Ploom TECH, KT&G (Korea) markets lil, and Imperial Tobacco is test-marketing Pulze.

### What is IQOS?

Philip Morris International (PMI) started selling IQOS products in 2014 in Japan, and has expanded sales to at least 50 countries. In the countries where the products are currently for sale, newer versions of IQOS have been released since the initial launch.

Consumers buy a device kit, which comes with a charging pack, a heating device, and components such as cleaner brushes and charging cords. HeatSticks, branded in some countries as Marlboro HeatSticks and branded in others as HEETS, come in packs of 20, like cigarettes, and are sold and marketed separately from the devices. Depending on the country, HeatSticks or HEETS are available in a variety of flavors, including berry, menthol, and menthol varieties ("Smooth Menthol"), and less obvious options such as "Amber Label," "Yellow Label," and "Turquoise Label." HeatSticks contain approximately half the amount of tobacco in a traditional cigarette.



In order to sell IQOS in the United States, PMI applied for and received a marketing order from FDA. PMI has contracted with Altria to market IQOS in the United States.

Unlike in some countries, HeatSticks are being sold under the Marlboro brand name. PMI filed a supplemental premarket tobacco product application (PMTA) for a newer version of the device, IQOS 3, on March 30, 2020. This version has been sold in other countries since late 2018 but is not yet allowed to be sold in the United States.

PMI also submitted a separate “modified risk tobacco product” (MRTP) application with FDA, requesting to make claims in its marketing materials about the reduced risk of using IQOS relative to using conventional cigarettes. An order from FDA is required before the company can make such claims in the United States. On July 7, 2020, FDA granted PMI the MRTP orders for the IQOS system. FDA denied PMI’s request to market IQOS as a “reduced risk” MRTP, finding there was not enough evidence that switching completely to IQOS “presents less risk of harm than continuing to smoke cigarettes” or “can reduce the risks of tobacco-related diseases.” However, FDA authorized a specific “reduced exposure” claim about an individual’s exposure to harmful chemicals:

“AVAILABLE EVIDENCE TO DATE:

- 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.”

Importantly, FDA did not find either that IQOS is “safe” or even “safer” than conventional cigarettes, or that IQOS can help smokers quit. Thus, PMI is not allowed “to make any other modified risk claims or any express or implied statements that convey or could mislead consumers into believing that the products are endorsed or approved by the FDA, or that the FDA deems the products to be safe for use by consumers.”<sup>4</sup> The exposure modification order expires in 4 years. To renew the order, PMI must file a renewal application prior to the expiration date.

### **IQOS Market in the U.S.**

Altria began selling IQOS in September 2019 in Atlanta, GA,<sup>5</sup> expanded its sales to Richmond, VA in November 2019 and to Charlotte, NC in July 2020, and announced that it would bring IQOS to four additional cities through 2021.<sup>6</sup> HeatSticks are being sold in those cities as well as surrounding metro areas; by the end of August, Altria “expects *HeatSticks* to be sold in more than 700 retail stores” (italics in original).<sup>7</sup>

### **Awareness and Use of HTPs**

Surveys and studies are just beginning to report on these products in the U.S., so currently trend data for adults and youth do not exist. However, the available data thus far can provide a baseline for comparison going forward.

**Adults.** A study surveyed U.S. adults in 2017 and found that less than one percent had ever used a heated tobacco product, but more were aware of the products.<sup>8</sup> The very low use rates are reflective of the fact that heated tobacco products, particularly the newest generation, were not yet officially on the market in the U.S.

A survey of U.S. young adults primarily in California in the year leading up to the release of IQOS onto the market, from August 2018 to July 2019, found that 12 percent were aware of HTPs and 5 percent had ever used them. More concerning, the survey found that about 14 percent of those reporting ever use of HTPs had never used any other tobacco product and multiple tobacco product users were more likely to report using HTPs. Data also found that young adult tobacco users in this survey who also used HTPs were more likely to be cigarette-dependent, but did not necessarily consider using them to transition away from combustible tobacco products, which suggested that they saw them as just another type of nicotine or tobacco product to use.<sup>9</sup>

**Youth.** The 2019 National Youth Tobacco Survey (NYTS) found that 12.8 percent of high school and middle school students reported awareness of HTPs, 2.4 percent reported ever use of HTPs, and 1.6 percent reported use of HTPs in the past 30 days. In addition, the researcher analyzing the survey found that “current tobacco use is associated with higher odds of HTPs ever and current use.” One limitation of the survey was that it was fielded in early 2019, around the time FDA had authorized IQOS and Eclipse to be sold by FDA, but neither of these products were actually on the market at that time.<sup>10</sup>

A survey of youth in Canada, U.K., and U.S. conducted in July and August 2017, before the products were introduced in the U.S., found that 9.1 percent of U.S. youth were aware of IQOS, compared to 6.4 percent in Canada and 5.6 percent in the U.K., where the products were already being sold. In addition, U.S. youth had significantly high levels of awareness, interest in trying, and susceptibility to trying IQOS among experimental, former, and current e-cigarette users, compared to never e-cigarette users.<sup>11</sup>

### **What is known about IQOS?**

There is a big knowledge gap about both the short and long term health impacts of HTPs. They have not been on the market long enough to be extensively studied under real-world conditions, and there is very little independent evidence to demonstrate that they are less harmful than conventional tobacco products or that they can help smokers quit smoking entirely.

The majority of currently available evidence on potential health effects is industry-funded, and the tobacco industry has a long history of funding research to support its business objectives.<sup>12</sup> The tobacco industry claims that by heating the tobacco, rather than burning it as with conventional cigarettes, the harms associated with combustion are significantly reduced.<sup>13</sup> This makes review by FDA and other independent scientists critical. PMI provided FDA with more than 2 million pages of research as part of its IQOS MRTP application.<sup>14</sup> As part of that process, FDA’s Tobacco Product Scientific Advisory Committee (TPSAC) also analyzed that research and notably, expressed significant concerns about IQOS being marketed as an MRTP. Independent studies on the product are slowly being published, including some that challenge results submitted by PMI to FDA.<sup>15</sup>

### ***Characteristics of the Product and Health Risks***

- Heated tobacco products deliver a significant level of nicotine to the user.<sup>16</sup>
- Studies have demonstrated that heated tobacco products contain many of the same chemicals found in cigarette smoke, but that most of the chemicals identified are present at significantly reduced levels.<sup>17</sup> In reviewing the evidence presented to FDA, TPSAC found sufficient evidence to support the statement, “Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body’s exposure to harmful or potentially harmful chemicals.”<sup>18</sup>
- In granting PMI exposure modification order for IQOS, FDA stated in its decision summary, “Although the available scientific evidence shows that the IQOS system produces lower concentrations of many harmful and potentially harmful constituents (HPHCs) compared to cigarette smoke and the non-clinical data suggests a favorable toxicological profile of the IQOS system compared to combusted cigarettes, the overall body of evidence was not sufficient to demonstrate that completely switching from combusted cigarettes to the IQOS system reduces the risk of tobacco-related disease or harm.”<sup>19</sup> Related, in its exposure modification order for IQOS, FDA noted that the reduced exposure from IQOS use could be associated with reduced risk even though studies provided by PMI did not show that result.<sup>20</sup> When it met in January 2018, TPSAC voted that the evidence provided by PMI did not adequately support its proposed claim that “Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes.”<sup>21</sup>
- Evidence shows that consumers believe that claims about reduced exposure to chemicals means a lower risk. Analysis of PMI’s own data submitted in the MRTP application showed “that adult consumers in the USA perceive reduced exposure claims as reduced risk claims.”<sup>22</sup> When it met in January 2018, TPSAC noted concerns about this consumer confusion.<sup>23</sup> FDA did not adequately address this issue in its decision summary on the MRTP orders.<sup>24</sup>

- The design of the product itself could impact consumers' beliefs about IQOS. FDA stated in its decision summary authorizing IQOS as a MRTP, "The novel design of the product may contribute to these risk perceptions ["that [IQOS] is lower in risk than cigarettes"] in the same way that many consumers perceived that e-cigarettes were a less harmful alternative to cigarettes when their use was becoming more common."<sup>25</sup>
- A recent systematic review of literature on heated tobacco products found discrepancies in findings on measured tar, tobacco-specific nitrosamines (TSNAs), and secondhand emissions from aerosol from IQOS between independent studies and manufacturer-funded studies, with the manufacturer's studies generally showing results more favorable to IQOS. Specifically, the independent studies showed lower levels of tar, but manufacturer's studies showed lower levels of TSNAs and no particulate matter from secondhand emissions.<sup>26</sup> This underscores the need for independent studies.

#### ***Smoking Cessation and Potential for Dual Use:***

- In its decision summary authorizing IQOS as a MRTP, FDA stated, "The 6-month study showed that incomplete switchers or dual users (as defined by the applicant) had much smaller reductions in exposure biomarkers as compared with IQOS use, suggesting that disease or mortality risk is unlikely to be substantially reduced as a result of exposure reduction in dual users of cigarettes and IQOS."<sup>27</sup>
- Studies provided by PMI show large rates of dual use in several countries.<sup>28</sup>
- In its decision summary for the marketing order for IQOS, FDA noted, "Dual use of CC [conventional cigarettes] and IQOS appears likely."<sup>29</sup> Previously, TPSAC had found that, based on the evidence provided by PMI, it was unlikely that smokers in the U.S. would switch completely to IQOS and there is a significant likelihood that smokers would become long-term dual users of IQOS and traditional cigarettes.<sup>30</sup>
- Available evidence raises concerns that heated tobacco products are being used by some non-smokers.<sup>31</sup> At the population level, even use by one percent of all adult non-smokers translates into millions of users.

#### ***Effect on Youth:***

- PMI did not provide FDA with any evidence about the impact of the product on youth.<sup>32</sup> Population health benefits that may accrue to smokers could be undermined if youth start using these products, exposing them to nicotine and other hazardous chemicals.
- Because HeatSticks are being sold under the Marlboro brand in the U.S., there is concern that the popularity of that brand among youth may attract youth to IQOS and generally enhance the image of all Marlboro-branded products.<sup>33</sup> Marlboro cigarettes continue to be the most popular brand among 12- to 17-year olds.<sup>34</sup> In addition, Marlboro HeatSticks are being sold in convenience stores and other retail stores, which means these products are just as accessible and visible to youth as Marlboro cigarettes.
- IQOS packaging may be appealing to youth. The product packaging, sleek design, and IQOS stores resemble products that are attractive to youth.<sup>35</sup> After showing adolescents aged 16 to 19 images of an IQOS device and a pack of regular HeatSticks branded HEETS, researchers found that among youth never-users (never smokers and never vapers) in the U.S., susceptibility to trying IQOS was higher than for traditional cigarettes but lower than for e-cigarettes. About one in five of the never-users (21.8%) in the U.S. were interested in trying IQOS and more than one quarter of never-users (27.0%) showed susceptibility to trying IQOS. The researchers commented, "[q]ualitative evidence suggests that IQOS packaging and marketing may have particular appeal among youth and young adults, given the important role that technology plays in their lives."<sup>36</sup>
- The importance of determining the likely impact of new heated tobacco products on young people is underscored by the recent youth uptake of e-cigarettes in the U.S., to the extent that e-cigarette use among the young now exceeds use of cigarettes and other tobacco products in the U.S.<sup>37</sup>

## **IQOS Marketing and Messaging**

PMI has implemented an extensive marketing plan in countries where it currently sells IQOS. In presenting its U.S. marketing plan to FDA's TPSAC, the Vice President of Heated Tobacco Products for Philip Morris USA, Sarah Knakmuhs, stated, "we've also had the opportunity to learn from PMI's introduction of IQOS in markets outside the U.S."<sup>38</sup> The launch of IQOS in Atlanta, GA, has reflected many of the same elements of PMI's marketing of IQOS abroad.

IQOS is being marketed as a sophisticated, high-tech, and aspirational product.<sup>39</sup> Because youth and young adults are interested in such product categories, this approach raises concerns about youth appeal. PMI heavily markets IQOS in certain countries, often in ways that it cannot market its conventional tobacco products, including through outdoor advertisements, public displays, point of sale displays, sponsored parties and cultural events, product 'launch events,' partnerships with other businesses particularly related to fashion and design, branded vehicles, and social media.\*

**IQOS Stores.** Located in popular shopping areas, these stores use modern and sleek designs that mimic technology stores like Apple stores that are highly appealing to youth and young adults. As one design firm stated, these aim to create an "extraordinary so-called 'consumer experience.'"<sup>40</sup> IQOS representatives in the stores are meant to introduce potential consumers to the product and show how to use them.

**Marketing to the General Public.** Philip Morris USA stated that "we want to limit our reach to unintended audiences such as nonsmokers and youth," but it is clear from PMI's actions abroad that the company seeks a broad audience for its marketing. PMI has set up IQOS kiosks and extensive advertisements in shopping malls, train stations, airports, and other locations with ample exposure to non-smokers, including kids and teenagers.

IQOS displays have been placed in locations such as gyms, barber shops, and hotels, which have broad reach and clearly do not limit exposure to adult smokers. In addition, PMI has placed outdoor ads for IQOS in shopping areas and set up IQOS lounges at public festivals, auto shows, and sporting events that are attended by people of all ages. For instance, at a street food festival in Kyiv, Ukraine, where children were present, PMI associates interacted with people throughout the festival, not limited to the IQOS space, and were offering free samples.<sup>41</sup> PMI hosted an IQOS stage at the 2017 Belgrade Beer Festival.

**Sponsored Social Events and Parties.** PMI hosts elaborate IQOS-branded social events and parties, sometimes hiring popular music artists, DJs, and celebrities linked to the art, fashion, or design world, to associate the product with a party lifestyle. In Romania, the company sponsors a series of parties hosted by A Brunch Affair and sponsors a beach bar. At a party to launch the new IQOS 3 device in Milan, Italy, musician Jamiroquai performed. Rather than educating attendees about the product, these events renormalize and re-glamorize tobacco use. It is unclear if PMI verifies that all attendees are adult smokers, but in at least one case, an attendee who identified herself as a non-smoker thanked PMI over social media for inviting her to the event.

**IQOS + Fashion.** To glamorize the product and link it to sophistication and fashion, PMI has sponsored fashion and design events, such as Mercedes-Benz Fashion Days in Ukraine; partnered with designers such as Karim Rashid to create limited-edition IQOS charger covers; and entered into partnerships with several women's magazines, including in Russia and Italy, for projects that include designing IQOS covers and empowering women in the workplace. Other special edition or limited edition IQOS devices and chargers include "motor edition," to tie the products with the PMI-sponsored Formula One race car.

**Paid Social Media Marketing.** Images posted on social media platforms feature influencers and "IQOS team" members who have been paid by PMI to model with products, speak about and otherwise promote products, and attend glamorous parties, group dinners, or engage in other exciting activities that make

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\* Examples of IQOS marketing in various countries described below are available at: [https://www.tobaccofreekids.org/assets/content/press\\_office/2019/IQOS-mktg.pdf](https://www.tobaccofreekids.org/assets/content/press_office/2019/IQOS-mktg.pdf).

IQOS look like part of a desirable lifestyle.<sup>†</sup> Though the posts originate from outside of the U.S., the influencers have enough American followers that one post can potentially reach 1.06 million Americans.<sup>42</sup> This means that, even before receiving the order from FDA allowing PMI to market IQOS in the U.S., PMI already engaged in paid practices that advertise the product to a U.S. audience. PMI has the ability to minimize the exposure of those posts to Americans, but has not taken action to do so.

After *Reuters* reached out to PMI for comment on its extensive social media marketing in many countries using paid influencers, PMI abruptly announced that it would “suspend all of our product-related digital influencer actions globally” for IQOS.<sup>43</sup> However, PMI also claimed that social media marketing was needed to reach adult cigarette smokers.<sup>44</sup> In February 2020, PMI was still found to be using social media influencers in Ukraine to raise the image of IQOS.<sup>45</sup>

Although a spokesperson for Altria stated that the company “has a policy against using social media or influencers,”<sup>46</sup> a job opening for a “digital marketing specialist” was posted on Altria’s career website requesting applicants with “experience with social media content and influencers” to help “develop the strategy for brand engagement, activations and deployment via digital channels specifically, e-commerce, owned websites, social media and influencers” for IQOS.<sup>47</sup>

**Reduced Risk Messages.** As mentioned above, although FDA has granted an exposure modification order allowing IQOS to be marketed with a specific “reduced exposure” claim, the agency did not find the evidence sufficient to allow the company to make any statements about reduced risk.<sup>48</sup> Similarly, while TPSAC found there was sufficient evidence that “switching completely from cigarettes to the IQOS system significantly reduces your body’s exposure to harmful or potentially harmful chemicals,” the committee did not find that this evidence translates into reduced harm, nor that consumers would fully understand what that message meant. One survey study, which explored youth understanding and perceptions of the claims of reduced risk and reduced exposure that PMI proposed in its MRTP application, found that more than one in four youth did not understand “the term switching completely to mean exclusive use of IQOS and never smoking cigarettes again.”<sup>49</sup> Further, the study’s findings suggested that youth might interpret reduced exposure claims similarly to reduced risk claims. PMI has acknowledged that consumers mistakenly believe that reduced exposure means that IQOS reduces harm. The company has stated, “It appears likely that consumers will typically infer a degree of reduced disease risk, even where such inferences are explicitly contradicted by warning statements.”<sup>50</sup> Separate surveys and studies have found similar results.<sup>51</sup> However, that has not stopped PMI from making and implying such broad messages in company statements<sup>52</sup> and other marketing materials.

**IQOS Launch in the U.S.** Before IQOS was launched in the U.S., researchers found that PMI had already paid for ads to appear in the Google search engine when U.S. users searched for the term “heat-not-burn.” The ad used language to suggest FDA endorsement of IQOS and imply reduced risk, which is a violation of the FDA law. In addition, to visit the website at the link in the ad, viewers were required to accept or decline a note from PMI saying the website was not for advertising or marketing, even though it is clearly meant to promote IQOS.<sup>53</sup>

Altria introduced IQOS in Atlanta, GA, in September 2019, using many of the same elements PMI used in other countries. There are IQOS flagship stores in two malls, several mobile stores mostly in convenience store parking lots, and several pop-stores called “IQOS Corners” inside convenience stores. HeatSticks are sold in about 500 retail locations around Atlanta such as convenience stores, grocery stores, and other places where tobacco is sold. Like other IQOS stores, those in Atlanta are sleek and high-tech, and offer \$1.00 samples to adults who identify themselves as cigarette smokers. IQOS experts also offer to “treat customers to ‘drinks or appetisers’” based on their personal interests.<sup>54</sup>

Though the device is priced at \$100 and a carton of HeatSticks is priced at \$55, Altria has offered a promotion for bundle purchasing and signing up with PM USA at \$80.00 plus tax.<sup>55</sup> In one IQOS pop-up store located in the parking lot of a gas station in NC, a consumer reported spending less than \$60 for the device and five packs of Heatsticks, purchased at the gas station with a coupon obtained from the IQOS

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<sup>†</sup> Additional examples of IQOS marketing on social media are available at: <https://www.tobaccofreekids.org/media/2019/iqos-marketing>.

representative.<sup>56</sup> It is clear that the company views these types of discounts as a profitable return on investment. At its Q3 financial earnings call, Altria CEO Howard Willard stated, “when you look at somebody who purchases that bundle and then converts to IQOS over the course of the year, it’s a relatively small investment for the significant income stream that creates.”<sup>57</sup> Visitors to stores have received emails for a reward program “to exchange points for product coupons.”<sup>58</sup> Users can also get additional discounts for referring friends and earn rewards to get customizable parts for the device.<sup>59</sup>

Altria created the [getiqos.com](http://getiqos.com) website to learn more about the product, schedule appointments for IQOS trial or service, find stores, and register their devices. People must register and be age-verified to enter the website. Neither the device nor the HeatSticks are sold from this website, but accessories are, and signatures are not required upon delivery.<sup>60</sup> Altria has created an Instagram account for IQOS in the U.S.<sup>61</sup>

Since launching in Atlanta, Altria has expanded IQOS sales to Richmond, VA, and Charlotte, NC, with Heatsticks availability expected in over 700 stores in the three cities by the end of August 2020. Altria also announced that it would be bringing IQOS to four additional cities by the end of 2021.<sup>62</sup>

As part of the MRTP order for IQOS, FDA specifically requires PMI to conduct analysis on the impact of the reduced exposure message on the percentage of youth and young adults below the legal age of purchase who start using IQOS.<sup>63</sup> FDA must also carefully monitor Altria’s marketing strategies to ensure that it does not make unwarranted health claims and that it does not engage in the same marketing practices used abroad by PMI to broaden the appeal of IQOS beyond adult smokers to non-smokers, especially youth.

### **Regulating and Taxing IQOS**

FDA has categorized IQOS and the HeatSticks as noncombustible cigarettes. In its marketing order for IQOS and Marlboro HeatSticks, FDA stated that IQOS would be subject to the same regulations as other new tobacco products under its jurisdiction, including packaging and labeling requirements, ingredient reporting requirements, and advertising requirements. FDA is also requiring post-market surveillance of IQOS sales, use, and advertising.

Marlboro HeatSticks are categorized as cigarettes under the current definition of cigarettes in the federal tax code, and therefore are subject to the federal excise tax for cigarettes.

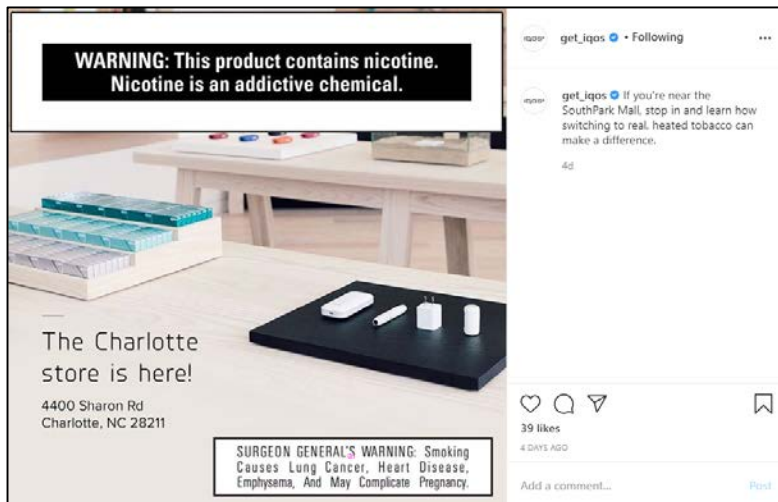
At the state level, definitions for cigarettes vary and while it is expected that the HeatSticks should be taxed as cigarettes, that may not be the case in every state. In addition, before receiving the marketing order for IQOS and HeatSticks, Altria approached state government officials in an effort to change the way HeatSticks would be taxed. In its 2017 second quarter earnings call, Altria’s CEO stated, “We have an engagement plan that we’re talking to public policy officials, to state tax officials and others...We are particularly pitching that in the states, but as you know, state excise tax structures are highly complex and idiosyncratic by state, so the reception varies from state to state. But we are out there sharing our views about that and trying as best we can to persuade people to be thoughtful about that.”<sup>64</sup> In 2019, Altria successfully persuaded Virginia lawmakers to exclude heated tobacco products from taxation as cigarettes by removing the word “heated” in the definition of “cigarettes” in the state tax code.

In its statement on FDA’s authorization to use specific reduced exposure messaging for IQOS, PMI stated, “the FDA’s MRTP authorization shows that IQOS is a fundamentally different product than combustible cigarettes, and must be regulated differently, as the FDA has recognized.”<sup>65</sup> However, because these products have not been shown to show any reduction in risk, it is premature to regulate these products differently than cigarettes.

Images from the U.S.

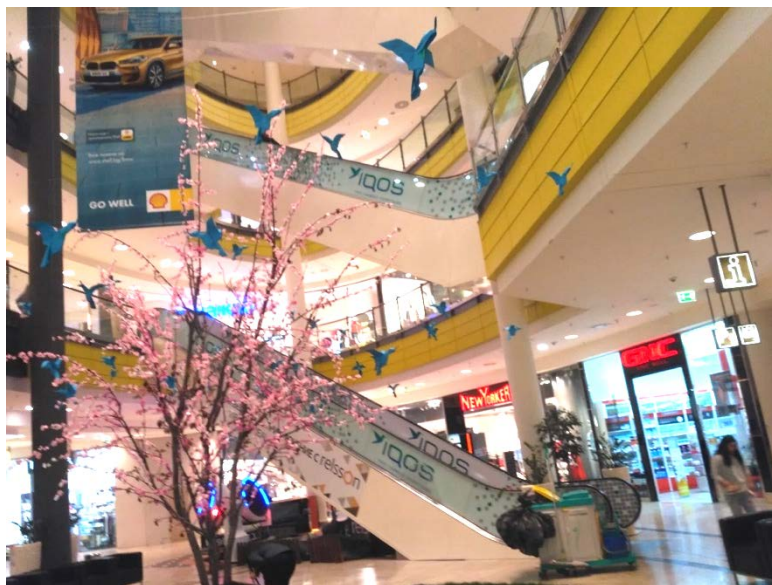


Images of the first IQOS store in the U.S., in Lenox Mall, Atlanta, GA. Tweet by Angelica LaVito, October 4, 2019, <https://twitter.com/angelicalavito/status/1180105485170728960>.



Post from the official U.S. IQOS Instagram account on the opening of the Charlotte, NC store, July 23, 2020, [https://www.instagram.com/p/CC\\_ShYjFBol/](https://www.instagram.com/p/CC_ShYjFBol/).

Images from Outside the U.S.



IQOS ads on sides of escalators and hanging hummingbirds (IQOS mascot) in a mall in Sofia, Bulgaria. Image taken April 19, 2018.

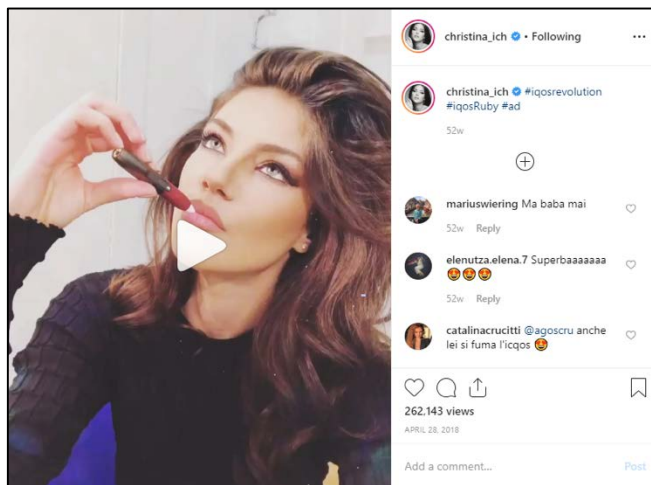




Mall display, Bulgaria. Image taken June 2018.



IQOS display in a gym in Italy. Instagram post from June 21, 2017, [https://www.instagram.com/p/BVm612BDnwb/?taken-by=iqos\\_friends](https://www.instagram.com/p/BVm612BDnwb/?taken-by=iqos_friends).



Instagram post by IQOS brand ambassador @christina\_ich (429k followers, nine percent in the US) that uses the hashtags #iqos and #ad. April 28, 2018, <https://www.instagram.com/p/BiH3JlrmAq/>.



IQOS at the Ulichnaya Eda street food festival, Kyiv, Ukraine, July 2017, <https://geometria.ru/events/other/2017/7/22/993787/pictures/62686985>.



"IQOS Zone," featuring a stage and lounge area at the 2017 Belgrade Beer Fest. Image by Goran Srdanov, at <http://www.telegraf.rs/vesti/beograd/2889153-nastup-grupe-sars-kao-kruna-jubilarnog-beer-festa-foto>.



Images from Shut Up, Beach!, an "IQOS friendly" beach bar in Mamaia, Romania, with extensive IQOS branding that is also venue for IQOS-sponsored parties. Instagram posts from August 6, 2018 and July 31, 2018, <https://www.instagram.com/p/Bml2yjWBxDz/>, <https://www.instagram.com/p/BI5yjVHhFaM/>. Facebook post from June 29, 2019, <https://www.facebook.com/shutupbeachRO/photos/a.157147491354639/765451963857519/?type=1&theater>.



IQOS 3 Motor Edition. February 8, 2019, <https://www.instagram.com/p/Btn5-RSILUv/>.

<sup>1</sup> New York Times News Service, "Battery-pack Puffer Aimed At Smokers," *Chicago Tribune*, October 23, 1997,

[http://articles.chicagotribune.com/1997-10-23/news/9710230178\\_1\\_nicotine-delivery-secondhand-smoke-benson-hedges](http://articles.chicagotribune.com/1997-10-23/news/9710230178_1_nicotine-delivery-secondhand-smoke-benson-hedges).

<sup>2</sup> Craver, R., "Reynolds' decision to stop marketing of heated cigarette Revo illustrates challenges in selling adult smokers on new products," *Winston-Salem Journal*, August 2, 2015, [https://www.journalnow.com/business/business\\_news/local/reynolds-decision-to-stop-marketing-of-heated-cigarette-revo-illustrates/article\\_afc1a516-29dc-55a5-8a54-75bd32cddd60.html](https://www.journalnow.com/business/business_news/local/reynolds-decision-to-stop-marketing-of-heated-cigarette-revo-illustrates/article_afc1a516-29dc-55a5-8a54-75bd32cddd60.html).

<sup>3</sup> U.S. Food and Drug Administration (FDA), letter to R.J. Reynolds Tobacco Company, July 19, 2018,

<https://www.fda.gov/media/115492/download>. FDA, letter to R.J. Reynolds Tobacco Company, November 14, 2019,

<https://www.fda.gov/media/138564/download>.

<sup>4</sup> FDA, "FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information," Press Release, July 7, 2020,

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