



### Episode Details:

Date of Publication: July 28, 2020

Title: Episode 18: Heated Tobacco Products

Description: This episode is designed to answer all your questions about heated tobacco products, or as the industry refers to them, "heat-not-burn" products. This episode covers their design and safety, assesses their marketing and current regulation, examines a bit of the newer research and literature on the products, explains the FDA's 'modified risk' label authorization for the IQOS Heated Tobacco System, and considers policy options moving forward.

### Transcription:

I'm Allie Rothschild and you're listening to the Counter Tobacco Podcast.

You may be hearing a lot more this month than usual about heated tobacco products. That's because the Food and Drug Administration just announced a monumental decision on how one of these products, the IQOS heated tobacco system, can be marketed here in the United States. But before we dive deeper into this, I want to start at the beginning and cover some of the basics. What are heated tobacco products? Are they really safer than cigarettes? What's all this news with the FDA? This episode is designed to answer all your questions on heated tobacco products, or HTPs. We'll look at their design and safety, assess their marketing and current regulation, examine a bit of the newer research and literature on the products, and consider policy options moving forward.

So, foremost, what are and are *not* heated tobacco products? The most basic definition of a heated tobacco product is an electronic device that heats tobacco which produces an aerosol inhaled by the user. These heated tobacco products are often called heat-not-burn products by the industry, but are actually considered by the FDA to be non-combusted cigarettes. This may be a little confusing to understand so I'm going to break this down by detailing one type or brand of HTP - the IQOS tobacco heating system. Now, IQOS is made by Philip Morris International, which split from Altria back in 2008. However, the two companies have partnered, under the Marlboro-brand Philip Morris USA to market the product together. Moving forward I'll refer to IQOS simply as a Philip Morris product, but I want to shed light on that quickly. So back to an explanation of the IQOS HTP – IQOS actually consists of three separate components. The first is a heating device - the best I can describe it is it looks like a slightly thicker version of a pen you would use to write with; one side is a mouthpiece where the user would inhale and the other side is hollowed out. This hollowed-out side is where you put the second component - the tobacco. For IQOS, Philip Morris sells Marlboro-branded tobacco Heat Sticks, which are also called HEETs internationally, that are to be used exclusively as the tobacco element for the IQOS device. These pretty much look exactly like cigarettes but slightly shorter. The HeatSticks contain tobacco, filters, and other added ingredients and are inserted into that hollowed-out side of the pen-like devices, where it can then be heated. And then the third component is a standard charging dock, which, for IQOS, kind of looks like a bigger version of an AirPods case, which is needed to recharge the pen-like heating device. I'll talk a little more about the design of IQOS and the HeatsSticks a bit later but for now I just want you to get a good mental image of the IQOS product so that you can understand what a typical HTP looks like and is composed of.



Now each HTP's design and how the tobacco is inserted and heated is going to look and be a little different for each manufacturer and brand, but all HTPs do a similar thing - they heat tobacco up to a certain, precise temperature that is far lower than conventional, combustible cigarettes and what this does is it creates an aerosolized and vaporized version of the tobacco that the user inhales. Conventional combustible cigarettes, on the other hand, when they are heated, ignite, burn, and create smoke. So the primary differences between your standard cigarettes and HTPs are how they are heated and to what temperature. These elements produce different outcomes - so for conventional cigarettes, you light them and they produce smoke, and for HTPs, you heat them and they produce vapor or aerosol. You may ask, what then is the difference between HTPs and e-cigarettes? For HTPs, the device heats tobacco leaf which creates an aerosol containing nicotine. For e-cigarettes, the device heats an e-liquid, which usually has nicotine that is derived from tobacco, flavorings and other artificial ingredients, and creates an aerosol of those components.

The concept behind HTPs is that the devices and products are supposed to psychologically and physically mimic a smoking experience similar to that of conventional cigarettes, while being a safer alternative. It has been proven time and again that burning and igniting tobacco through conventional combustible cigarettes generates thousands of chemicals and toxins, which are harmful to the people smoking them and those otherwise exposed to the second-hand smoke. The industry claims, on the other hand, that HTPs, which heat rather than burn the tobacco, are safer and less toxic than conventional combustible cigarettes. They also claim these products produce fewer chemicals and reduce the impact on heart and lung health, particularly for those who switch entirely from cigarettes to HTPs.

I use the word 'claim' here because when I critically look at the evidence that has been presented and the research that has been published I start to see some things that are a little alarming from the perspective of a public health professional. First, as these products are relatively new to the market, especially here in the US, there's really only a small amount of research that exists on the both the short- and long-term health effects of using and being exposed to the product and the aerosolized tobacco. Second, there is no independent verified evidence that HTPs do indeed present a reduced risk of harm. Some studies have shown that HTP users may be exposed to less chemicals, but they haven't demonstrated any evidence that this reduced exposure ultimately leads to reduced risk of morbidity or mortality. Third, and most shocking of all to me, is that most of the research published in the US has been led, funded by, or otherwise associated with the tobacco industry. Thousands of leaked industry documents over the years have evidenced that Big Tobacco has a fraught history of misinforming the public of the harmfulness of their tobacco products, so it's worrisome that a significant portion of the 'evidence' of the reduced harm of HTPs has been conducted by the industry itself.

Beyond my assessment, which mimics many of those in the public health field, the FDA, who I'll talk a little more about in a bit, maintains that HTPs are neither safe nor FDA-approved. The World Health Organization has stated that there's no evidence that HTPs are less harmful than conventional cigarettes; they also have stated that the industry has not done enough to prove that the reduced exposure to chemicals and toxins from these products actually translates into reduced risk of harm. The CDC has noted that the use of any tobacco product, which includes HTPs, is harmful and unsafe and that research has not sufficiently proven that these products help people who smoke to quit. The CDC does recognize that the aerosols generated by HTPs generally have lower levels of harmful ingredients, toxicants, and particulate matter than the smoke from cigarettes, but, on the flip side of the coin, the HTPs do have many of the same harmful ingredients as cigarettes, and even some additional dangerous ones not found in your conventional cigarettes. In some instances, the HTPs actually produce higher concentrations of some of the carcinogens that a conventional cigarette would produce. And actually, when Philip Morris conducted its own testing of the vapor generated from their Marlboro HeatSticks, they only found 10 compounds in the aerosol; but



when independent researchers more recently used a different process with greater specificity and sensitivity, they found 62 compounds in the vapor, with many of these compounds being considered toxic. As well, regardless of how they heat the tobacco, these HTPs still contain nicotine, which has proven to be highly addictive and particularly dangerous for developing adolescent brains. Additionally, HTP vapor, just like cigarette smoke, contains toxic chemicals which can cause serious health consequences like cancer and heart disease. So overall, most medical and public health practitioners have come to the conclusion that sufficient evidence does not exist to prove that HTPs are less harmful than conventional cigarettes.

Now, we're going to transition here and talk a bit more about marketing and regulation of HTPs. There are a handful of different brands and manufacturers of HTPs, and they have a much bigger presence internationally, but the only ones currently permitted to be sold here in the US are RJ Reynolds' Eclipse, which has seemingly been discontinued, and Philip Morris' IQOS, and since the latter is the more popular and well-known of the two and still on the market, I'm going to focus most of the rest of the conversation on IQOS. So IQOS was authorized for market in the US by the FDA in April of 2019, so like I've mentioned, it's a very new product here. The FDA's decision to allow the product on the market was controversial at that time and still is. In terms of regulation, the FDA determined that the product would be considered a non-combusted cigarette and, as a result, the IQOS heated tobacco system is regulated federally in the same way that conventional, combustible cigarettes are. The device was first rolled out in late 2019 in Atlanta, Georgia and then shortly after, Richmond, Virginia was selected as a second test market. The devices themselves were and continue to be sold primarily at flagship stores, malls, mobile units, and kiosks. The HeatSticks are sold in these locations as well but were also rolled out to conventional tobacco retailers in these cities. The HeatSticks come in packs of 20 and in menthol and non-menthol versions, similar to cigarettes. They are also marketed under the Marlboro name, which is one of the most preferred brands of youth and young adults, and one of the most well-known and recognized lines of tobacco products. Philip Morris' conscious tying of the Marlboro name to the new IQOS system is likely a strategy used to increase brand recognition and appeal for the product right from the get go. As well, the HeatSticks, as I said, come in a menthol flavor. Menthol tobacco products are designed in a way that makes smoking easier and quitting harder, are generally more attractive to a younger demographic, and have long been targeted to Black and Brown consumers.

I briefly mentioned this before when I said that the IQOS charger looked a lot like an AirPods case, but the design and aesthetic of IQOS is very sleek, sophisticated, and stylish. The charging component is about the size of an iPhone but is designed like the AirPods case so that you can insert the pen-like heating system into the charging dock and close the lid. Both the charging case and heating device come in a handful of bold and opulent colors - white and black with gold accents, royal blue, rose gold. I have some images up and they look very savvy and high end. The Campaign for Tobacco-Free Kids put out a great PowerPoint documenting the global marketing of IQOS. I'll link it in the show notes but they include some really great pictures. From the looks of it the flagship IQOS stores both in the US and abroad have a remarkably similar appearance to an Apple store, but with a slightly less minimalistic design and a bit more of a pop of color. They have seating areas with sofas, and wooden tables and displays with products lined up so that, again similar to an Apple store, you can go in and touch and play around with products. And abroad, they do product samplings in their stores as well. Globally, IQOS has sponsored and branded street food festivals, parties at night clubs, concerts, music festivals, and art contests. They had IQOS branded cars driving around in Eastern Europe and launch events in South Africa with acrobatics for entertainment. I say all this to show that Philip Morris has expended a wealth of money to market this product as fun and flashy, cool and creative, and stylish and sleek. Here in the US, the flagship stores do currently require guests be 21 years of age to enter and apparently there are screeners positioned at the door to narrow the customer base to only adults who smoke. However, there remain significant concerns about the products appeal to youth based on these marketing efforts, branding, and product design.



And now, here's where the FDA comes in - the FDA, just this month, authorized Philip Morris to market its products as 'modified risk'. The IQOS device and accompanying HeatSticks are only the second set of products ever to be authorized to use this type of label and the first to receive authorization specifically for a “modified exposure” claim. So in addition to all the marketing and branding they are already doing, Philip Morris can now legally market the claims that IQOS significantly reduces the production of harmful and potentially harmful chemicals and that 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 products.

I want to pause and make an important distinction here. While the FDA approved IQOS being marketed as a “modified risk tobacco product,” they only actually approved the claims that the product reduces exposure, and they denied the company's request to market the product with claims of risk modification. This means that Philip Morris cannot claim that use of the products presents reduced harm or a lower risk of tobacco-related disease – only that the products offer reduced *exposure* to harmful chemicals. There is a major concern that, despite this, customers may perceive the products and their new “reduced exposure” label to mean “reduced harm.”

In addition, don't forget all that I've mentioned about harmful chemicals and addictive nicotine, the industry-funded research, and the abundance of marketing and sponsored events intended to lure customers. So undoubtedly, public health and medical professionals have some serious concern. They're worried that IQOS may be just another product, similar to e-cigarettes, that will attract and addict a new segment of the population, specifically people who do not currently smoke and youth. They're also worried that a product that claims to be safer than conventional cigarettes may re-normalize smoking and tobacco use, which over the past few decades has significantly declined. There really isn't a lot of research out there on the impact these HTPs have on smoking cessation, whether they're attractive to younger generations, and what the effects are for someone who may pick up HTP use in addition to a secondary tobacco habit or addiction to e-cigarettes, conventional cigarettes, or any other tobacco product.

There is, fortunately, more independent research that is starting to trickle out and be published, so I do want to touch on some of those briefly. One international study found that the product likely has appeal to youth and young adults, given the IQOS marketing portrays these products as "akin to iPhones", which may attract a younger, more tech-savvy generation; another international study found that exposure to advertising of HTPs was associated with perceptions that HTPs were less harmful than conventional cigarettes. A qualitative study out of the UK looked at reasons and barriers to use. And I want to mention these so that you can get an idea of who is using these products and why. They found adults reported using HTPs for six primary reasons. (1) Health - people reported wanting to quit smoking and they perceived these devices to be reduced harm and useful tools for smoking cessation. (2) Financial - long-term use is generally cheaper for HTPs versus combustible cigarettes. (3) Physical - HTPs were reported as being clean, discrete, having less of an odor and offering a similar tactile experience to smoking regular cigarettes. (4) Practical - respondents noted that they were able to smoke HTPs in smoke-free places and that this improved accessibility was a positive attribute of the device. (5) Psychological - respondents stated HTPs provided a similar feel and routine to smoking combustible cigarettes and some liked the novelty of the device. (6) Social - respondents also mentioned improved social interactions since they could use these devices around people who do not smoke. Barriers to HTP use included high upfront costs, reduced satisfaction, and maintenance issues. In this study, participants also reported beliefs that IQOS was less harmful than conventional cigarettes due to less alarming health warnings and a lack of graphic health warnings.

The last thing I want to talk about with research is prevalence. The CDC only began tracking use of HTPs in 2017 and at that point less than 1% of US adults reported ever using an HTP with roughly 3% of these individuals being people



who currently smoke cigarettes. By 2018, which is the most current US data we have, prevalence of HTP use had more than doubled to 2.4% of adults, with roughly 7% of these individuals being people who currently smoke cigarettes. That's pretty much all the prevalence and demographic data we have here in the US. So as an indicator of potential trends, I want to mention a more recent study out of Japan, where HTPs have been on the market for longer. In a survey of over 8,000 participants, ages 15-69, researchers saw a massive spike in HTP use from 0.2% in 2015 to 11.3% in 2019. Use was more than 10% higher in men compared to women, participants in their 20s and 30s compared to older aged individuals, and people who currently smoke compared to people who formerly smoked and people who have never smoked. There aren't any statistics or research on youth use yet but I did come across one study published in December 2019 about American youth perceptions of IQOS. Using data from 2017, researchers found that 9% of American youth were aware of IQOS and 41% expressed interest in trying IQOS, which is, in my opinion, exceedingly high given IQOS was not even being marketed in the US at the time of data collection.

As we wrap up here, I do want to briefly touch on a few policy options at the state and local level. Foremost, it's absolutely necessary that any new policies are written with language that includes HTPs and that already established ordinances and polices are amended to include HTPs if their definitions are not comprehensive enough to do so already. Second is licensing. We have a whole episode on tobacco retailer licensing that could be a good starting point to learning more on this topic but we recommend that retailers who sell HTPs, if they are not already, be licensed to do so. Licenses are also a great way to incorporate multiple tobacco -related provisions as well as put in place a plan for enforcement. The next three options are really applicable to any tobacco product, heated tobacco product, or electronic nicotine device and are recommended to counter these items directly at the point of sale. The first is implementing price policies such as minimum price floors and restrictions on discounts, coupons, and promotions. The second is prohibiting the sale of flavored products, which includes menthol. If you remember, HeatSticks do come in a menthol flavor so implementing a ban on flavors would take these off the market. And the last suggestion is reducing or restricting advertising and marketing, especially any tactics, displays, or advertisements that are geared towards youth.

To close out there's two final statements I want to make. First - remember that there is no such thing as a safe tobacco product. HTPs are tobacco products and tobacco products are comprised of highly addictive nicotine and harmful chemicals that may have long-lasting health effects. The second is a quote from prominent tobacco researcher, Dr. Stanton Glantz, from a commentary he wrote for the journal, *Tobacco Control*. He writes, "[Heated tobacco products] are the latest effort by tobacco companies to adapt to a changing regulatory landscape to maintain and expand their customer base amid declining social acceptability of tobacco use and declining cigarette consumption. ...Where regulations are absent or loopholes exempt [heated tobacco products] from existing regulations, companies market [heated tobacco products] to increase social acceptability for all their tobacco products."

In summation, we here at CounterTobacco.org believe it's of critical importance that independent researchers and those in the field of tobacco control continue to assess the risk of harm of these products and routinely monitor how these products are being marketed and sold. The new modified risk claim awarded to IQOS will likely impact perceptions of harm, so there is a real need to keep a finger on the pulse of how IQOS is being marketed in this country, especially among youth and young adults. As well, the industry is notorious for targeted marketing of menthol products to Black and Brown communities so we must keep an eye on whether disparities in marketing are present and leading to inequities in use and health outcomes.



As always, I will include all my sources and some great resources in the show notes. If you ever have any questions or suggestions for future episodes, you can email us at [info@countertobacco.org](mailto:info@countertobacco.org). I appreciate you listening to the Counter Tobacco Podcast and I look forward to you joining me again next time.