



# Understanding Heated Tobacco Products: Current Issues and Recent Findings

Sales of heated tobacco products (HTPs) are on the rise around the globe. The tobacco industry markets HTPs as "reduced risk" products and claims they are a better alternative to cigarettes.

In reality, the evidence is not so clear-cut, and there are numerous examples of the industry marketing HTPs to a wide audience, including children—not just to smokers.

Given the lack of conclusive, independent evidence on the safety of HTPs, and the industry's history of making misleading claims around its products, policymakers and the public should remain wary of the industry's promotion of HTPs.



Credit: Ploom: Editorial credit: Ammatar / Shutterstock.com. IQOS: Gevorg Simonyan / Shutterstock.com. Glo: ElenaVah / Shutterstock.com.

### What is an HTP?

HTPs are often mistaken for electronic cigarettes (e-cigarettes). Though both products are electronic devices, HTPs contain tobacco, while e-cigarettes do not. The tobacco component of an HTP contains a combination of tobacco, water, glycerin, fibers and guar gum paste that is formed into rods or sticks.<sup>1</sup> Sold separately, the sticks are inserted into a device that heats them, releasing highly addictive nicotine and other chemicals. There are also hybrid HTPs that contain both a liquid and tobacco.

The first iterations of HTPs were developed in the 1980s but saw little commercial success. In the face of declining cigarette sales after years of successful tobacco control measures and the introduction of e-cigarettes threatening their business, tobacco companies revived the technology in the mid-2010s. By 2019, the "Big Four" tobacco companies—Philip Morris International (PMI), British American Tobacco (BAT), Japan Tobacco International (JTI) and Imperial Brands—had each launched an HTP, dominating the market.<sup>2</sup>

#### **Market Positions of the Big Four**

Source: Euromonitor



\*The state-owned China National Tobacco Company controlled 46.9% of global cigarette sales in 2023 but is not a major player in the HTP market.

## Independent research casts doubt on the industry's "smoke-free" claims

The tobacco industry promotes HTPs as "smoke-free" or "non-combustible." They claim HTPs do not combust, or burn, tobacco, but rather heat it to a temperature sufficient to release an aerosol containing nicotine and other harmful or potentially harmful chemicals. Several studies cast doubt on the industry's "smoke-free" claim. One study specifically on PMI's IQOS, which leads the HTP market, found "emissions fit the definition of being both an aerosol and smoke."<sup>3</sup>

Before entering the market with their own brands, even some of the Big Four tobacco companies described HTP emissions as smoke. In its published research, PMI described the emissions of its IQOS prototype as "smoke."<sup>4</sup> Imperial Brands published a study showing IQOS produced "side-stream emissions" (aka secondhand smoke) and concluded it should be regulated under smoke-free legislation the same as cigarettes.<sup>5</sup>

Promoting HTPs as "smoke-free" is beneficial to the industry for several reasons. First, it is integral to Big Tobacco's transformation narrative, in which the industry claims to be phasing out cigarettes as part of an evolution toward being more health-conscious and sustainable. The Big Four promote HTPs in the context of innovation, technology and better health. Yet it is clear the tobacco companies' original intent was for HTPs to be sold in addition to cigarettes, not replace them.

Financial statements from the Big Four support this notion: the Big Four are still selling an estimated 1.85 trillion cigarettes a year, and none of the companies appear to be taking active steps to reduce cigarette sales. Instead, they're buying cigarette companies,<sup>6, 7, <sup>8, 9, 10, 11</sup> opening new factories<sup>12, 13, 14, 15, 16, 17</sup> and targeting countries with fewer or laxer tobacco control laws. They're very much working to maintain cigarette sales in any way they can. PMI and JTI even claim that maintaining cigarette profits is necessary to expand the market shares of their HTP and other "reducedrisk" offerings.<sup>18, 19</sup></sup>

Second, marketing HTPs as "smoke-free" may persuade policymakers to regulate the products more loosely. A "smoke-free" label could help tobacco companies attain favorable tax status on HTPs, which would make them more affordable and accessible—a goal identified in leaked documents from PMI.<sup>20</sup> Independent academics have also suggested another motivation for the "smokefree" label would be to circumvent smoke-free laws, which would permit HTPs to be used in places where smoking is banned.

## Emerging evidence uncovers the risks of HTPs

Researchers at the University of Bath examined data from clinical trials assessing HTPs. They looked specifically at biomarkers of potential harm, which determine whether harm happened to a user as a result of exposure to toxicants.<sup>21</sup> They found that the data, which the industry is citing to promote HTPs as a better choice than cigarettes, is far from conclusive.

The researchers found that HTP use caused harmful effects in both cigarette smokers and non-smokers, and that benefits in smokers were limited or inconsistent. This was the case even in smokers who made a complete switch to HTPs, in which one would expect to see mostly or only beneficial effects, based on tobacco companies' "reduced risk" marketing claims.

In one example, researchers examined measurements of blood pressure in both controlled (confined) and realworld (ambulatory) settings. In a controlled setting, most studies the researchers reviewed showed less harm to systolic and diastolic blood pressure following shortterm HTP use compared to cigarette use. However, in real-world settings, some studies indicated HTP use caused more harm, some indicated it caused less harm, while another showed no difference in harm compared to cigarette use.

## Effect of HTPs on Blood Pressure Compared to Cigarettes

#### **Controlled Settings**

Diastolic blood pressure

Systolic blood pressure

#### **Real-world Settings**

Diastolic blood pressure Systolic blood pressure

More Harmful



# of Studies



Adapted from Figures 1 and 2 of "<u>The impact of heated tobacco</u> products on biomarkers of potential harm and adverse events: a systematic review and meta-analysis"



Abdominal x-ray showing a sharp metallic susceptor from an HTP in a 7-month-old's stomach. Reprinted from Higashi et al., <u>Extraction of</u> <u>a metallic susceptor after accidental ingestion of the heated tobacco</u> <u>product TEREA<sup>™</sup>: a case report.</u>, under a CC BY 4.0 licence.

Findings were also mixed when comparing HTP use to e-cigarette use and quitting smoking. Researchers noted the paucity of data comparing HTPs to e-cigarettes and quitting smoking, which hinders any estimation of their relative safety. "Overall, the findings are so mixed that these data provide no clear indication of the relative risks/benefits of HTPs, even compared to cigarettes," researchers concluded.

Other clinical evidence reveals potential harms of HTPs, including incidents in which HTPs have led to hospitalizations: Children have ingested not only the tobacco sticks, but also the heating blade and other metal components in the devices;<sup>22, 23</sup> a man once consumed numerous menthol heat sticks, introducing a potentially lethal dose of nicotine to his system;<sup>24</sup> and a rare form of pneumonia has been reported in people using HTPs,<sup>25</sup> combining conventional cigarettes and HTPs<sup>26</sup> or switching from cigarettes to HTPs.<sup>27</sup> Independent studies show HTP emissions still contain carbon monoxide and other constituents found in cigarette smoke. Included are volatile organic compounds and harmful and potentially harmful constituents, some of which are found in higher concentrations in HTP emissions, including carcinogens.<sup>29, 30</sup> Perhaps most worryingly for a product whose popularity is on the rise, there is little to no appropriate clinical data available for assessing the risk of lung cancer in smokers or nonsmokers who take up HTPs. This, despite an estimated 80-90% of cases of the deadly disease stemming from smoking.<sup>31</sup> While the research done thus far cannot support claims of safety, there is evidence that suggests HTPs are harmful, given the delivery of nicotine and chemicals, their negative effects on biomarkers and cases of hospitalization. They are not risk-free, as the tobacco industry acknowledges, meaning they pose risks of disease and addiction. HTPs can only do harm when used by non-smokers. Contrary to the industry's claims, the evidence indicates HTPs can still harm smokers' health, and their relative risk compared to cigarettes remains largely unclear.

### The Harmful Life Cycle of HTPs



# Are HTPs really intended for adults who are trying to quit cigarettes?

The industry claims HTPs are only intended for adult smokers. Numerous studies have debunked this notion, documenting high rates of usage among youth,<sup>32, 33, 34,</sup> <sup>35, 36, 37, 38</sup> who are more likely to be nonsmokers. A 2023 study found that, globally, adolescents are more than twice as likely as adults to have used HTPs.<sup>39</sup> It is unlikely that this is an undesired side effect of pushing HTPs to market, as substantial evidence shows PMI specifically targets audiences beyond adult smokers via festivals, events<sup>40</sup> and publications popular with young people.<sup>41, 42</sup>

PMI claims more than 23 million adults have switched to IQOS and stopped smoking cigarettes. But PMI's estimates do not reflect real-world data. Both independent and PMI data show the majority of IQOS users continue smoking. Independent research has also found:

- Many HTP consumers continue to use other tobacco and nicotine products.<sup>45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55</sup>
- Some studies show insufficient evidence about whether HTPs help smokers quit, while other studies show HTP use does not help smokers reduce or quit smoking.<sup>57, 58, 59</sup>

PMI changes its marketing message around IQOS depending on location. In some countries, PMI and the industry promote HTPs as cessation aids (despite independent data not supporting this), while in others it states the devices are not an alternative to quitting, nor are they designed to be cessation aids.<sup>60</sup> While this may be a function of different nations' advertising laws, these contradictory messages stoke confusing and misleading messages about the purpose of IQOS and who its intended audience is.

True harm reduction would require the fulfillment of two fundamental factors: that HTPs pose a proven, longterm reduced risk of disease and death when compared to cigarettes, and that they are used only by smokers. In everyone else—including nonsmokers and especially children—HTPs can only increase harm.

The bottom line? Even if HTPs could be less harmful than cigarettes, true population-level harm reduction is

unachievable if nonsmokers use them. Data thus far does not prove that HTPs aid cessation, and their short- and long-term impacts on health remain unclear.

# The tobacco industry uses biased science to promote HTPs

Through two systematic reviews examining literature up to December 2024,<sup>61</sup> University of Bath researchers identified 49 clinical trials on HTPs. Only a few of these studies were independent, and 34 were affiliated with or conducted by a tobacco company. Indeed, a significant portion of the trials (16) came from just one source: PMI. Reflecting concerns over the quality of these trials, the risk of bias was rated high for 39 of them and unclear for the remaining 10. The clinical trials conducted to date were not representative of real-world use, researchers found. They were largely of short duration, conducted under laboratory conditions and failed to include outcomes or comparisons to other interventions, information that would better inform public health.

The tobacco industry has a decades-long history of influencing and manipulating science to support the use of its products. Each of the Big Four has utilized third parties, sometimes appearing to be independent from the industry, to attack independent science and mislead the public on tobacco harms.<sup>62</sup> For example, JTI funds the Smoking Research Foundation,<sup>63</sup> and PMI created and was the sole funder of the Foundation for a Smoke-Free World (now called Global Action to End Smoking [GAES]).<sup>64</sup> While PMI's funding agreement with GAES has ended, GAES is still operating on tobacco funds after PMI gave a final payment of US \$140 million.<sup>65</sup>

In seeking influence, Big Tobacco promotes its own research via multiple mediums. The Big Four have dedicated "science" websites on which they can disseminate their desired scientific rhetoric without peer review or oversight.<sup>66</sup> BAT and PMI have also attended scientific events, providing a platform to build connections in the scientific sphere and spread the industry's misleading messages. Their presence also serves to normalize tobacco industry involvement in research and science, despite its obvious conflicts of interest.<sup>67</sup>



IQOS stand in a petrol station, Greater Manchester, UK. November 2024.

## How PMI Tries To Manufacture Support For Harmful Products

Despite inconclusive data on safety and cessation claims surrounding HTPs, the industry continues to push for regulations that would broaden HTP availability and affordability. Leaked documents show that, in striving to manufacture broad support for IQOS, Philip Morris Japan (PMJ) secretly funded a Kyoto University study on smoking cessation. PMJ also paid a life sciences consultancy hundreds of thousands of dollars for science-adjacent work, including forging ties with scientific opinion leaders and promoting PMI science and messaging at academic events.

The leaked PMJ documents reveal the company had a multi-pronged plan to manufacture widespread regulatory and societal support for IQOS. This meant accelerating "acquisition and conversion of new users" in other words, part of the plan was to increase IQOS addiction throughout Japanese society. Japan was a launch market for IQOS, so it provided proof-of-concept for PMI's marketing strategy. There was little risk for PMI in targeting Japan: Electronic cigarettes are banned, so IQOS had minimal competition.



A 2024 earnings press release states the company shipped 139 billion HTP units, up from 7 billion in 2016, an increase of over 1,885%.

Further evidence reveals PMI's global efforts to reach young people with its products, using sleek designs for its devices and promoting IQOS via avenues popular with youth, including influencers,<sup>68</sup> social media,<sup>69</sup> gaming,<sup>70</sup> Formula One,<sup>71</sup> concerts and festivals.<sup>72, 73, 74</sup> It also engaged in peer-to-peer advertising that's shown to be highly effective with young people.<sup>75</sup>

PMI's methods to grow the HTP sector appear to be working. A 2024 earnings press release states the company shipped 139 billion HTP units,<sup>76</sup> up from 7 billion in 2016. That's an increase of over 1,885%. PMI now boasts 30.8 million IQOS users,<sup>77</sup> and "smoke-free" products\* compose 40% of the company's revenue.<sup>78</sup> Globally, HTP sales from all brands are expected to hit \$41.6 billion in 2025, an almost 29% increase over the \$32.3 billion two years prior.<sup>79</sup> Considering the billions the Big Four make off cigarettes, it's clear the industry is financially benefiting by selling both products.

<sup>\*</sup> According to its 2024 Integrated Report, PMI defines "smoke-free" products as: heated tobacco products (HTPs), e-vapor products, oral nicotine products, wellness and healthcare products and consumer accessories (e.g lighters, matches, etc.).



The "IQOS Terrace," Grandvalira Ski Resort, Andorra. December 2024.

#### Recommendations

There is a lack of long-term, independent research on HTPs. Regulators must demand or help attain funding for more independent, high-quality research—using realworld conditions and researchers unaffiliated with Big Tobacco—to fill evidence gaps. This includes unbiased clinical trials, population-level epidemiological studies, lengthier trials that measure the impacts of HTPs, studies on nonsmokers who start using HTPs, and comparisons against proven cessation aids.

While this data is gathered, policymakers and consumers should remain skeptical about industry claims. The independent data available suggests HTPs have the potential to harm smokers and nonsmokers, and are addicting a new generation to nicotine and tobacco. Finally, in the face of aggressive industry lobbying and a history of promoting misleading science, governments and policymakers must refuse demands to grant tax breaks or incentives to the industry, whose products cause health, environmental and economic harm. The tobacco industry cannot be rewarded for risking the health and lives of millions of people.

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#### About STOP (Stopping Tobacco Organizations and Products)

STOP is a global tobacco industry watchdog whose mission is to expose the tobacco industry tactics that undermine public health. Comprised of a network of academic and public health organizations, STOP researches and monitors the tobacco industry, shares intelligence to counter its tactics, and exposes its misdeeds to a global audience. STOP is funded by Bloomberg Philanthropies as part of the <u>Bloomberg Initiative to Reduce</u> <u>Tobacco Use</u>. For more information, visit <u>exposetobacco.org</u>.