

Vaping and e-cigarettes: Adding fuel to the coronavirus fire?

 abcnews.go.com/Health/vaping-cigarettes-adding-fuel-coronavirus-fire/story

By Dr. Chloë E. Nunneley 26 March 2020, 17:04 6 min read



Vaping and e-cigarettes: Adding fuel to the coronavirus fire? Because vaping can cause dangerous lung and respiratory problems, experts say it makes sense that the habit could aggravate the symptoms of COVID-19.

New data released by the Centers for Disease Control and Prevention last week warns that young people may be more impacted by COVID-19 than was initially thought, with patients under the age of 45 comprising more than a third of all cases, and one in five of those patients requiring hospitalization.

Although scientists still don't have good data to explain exactly why some young people are getting very sick from the novel coronavirus, some experts are now saying that the popularity of e-cigarettes and vaping could be making a bad situation even worse.

Approximately one in four teens in the United States vapes or smokes e-cigarettes, with the FDA declaring the teenage use of these products a nationwide epidemic and the CDC warning about a life-threatening vaping illness called EVALI, or "E-cigarette or Vaping-Associated Lung Injury."

Public health experts believe that conventional cigarette smokers are likely to have more serious illness if they become infected with COVID-19, according to the World Health Organization. Because vaping can also cause dangerous lung and respiratory problems,

experts say it makes sense that the habit could aggravate the symptoms of COVID-19, although they will need longer-term studies to know for sure.

Vaping may increase risk of serious COVID-19

Columbia University pediatrician Dr. Alok Patel, an ABC News special correspondent, points out that cases of EVALI provide very real evidence that vaping can cause direct lung damage, which puts e-cigarette users in the “high-risk bracket” of those most vulnerable to serious illness from COVID-19.

“We know that e-cigarettes include chemicals such as propylene glycol, glycerol, and flavorings, and that these chemicals have the ability to go deep into your lungs and cause damage,” Dr. Patel told ABC News. “When people become critically ill from COVID-19, this also involves the deep pockets of their lungs. It’s really scary to think about what could be happening in those that have both of these going on together.”

Worse still, many e-cigarette products contain massive amounts of nicotine, which has been clearly linked to significant negative effects on both the immune and cardiovascular systems.

“That alone is concerning,” Patel said.

In terms of just how vaping may lead to increased susceptibility to the novel coronavirus, Dr. Christy Sadreameli, pediatric pulmonologist at Johns Hopkins, explained that there are likely multiple mechanisms involved.

“Along with decreased mucociliary clearance,” which is how healthy lungs sweep away pathogens, Dr. Sadreameli said, “vaping can increase lung inflammation and may alter other pulmonary defense mechanisms, such as by decreasing the functioning of CFTR,” the protein that, when defective, causes cystic fibrosis.

Dozens of studies have also shown damage at the cellular level. Researchers have found that exposing lung cells to e-cigarette vapor decreases the effectiveness of immune cells responsible for fighting pathogens. And bacteria exposed to e-cigarette vapor also appear to become more infectious.

Long term impact of e-cigarette use

Vaping is still fairly new, with the rates of use drastically climbing just in the past few years.

“The most concerning thing from both a public health standpoint and as a pediatrician is that we don’t yet know the long-term effects of vaping,” Patel said.



An undated stock photo show a person on a ventilator.

An undated stock photo show a person on a ventilatorSTOCK PHOTO/Getty Images

Data is quickly mounting, however, and the results are sobering.

Adolescent e-cigarette users have been shown to have increased symptoms of chronic bronchitis, the same symptoms of chronic cough and phlegm that are seen in elderly patients with COPD.

"That goes along with the decreased mucociliary clearance," Patel explained. "Chronic bronchitis sets up a different milieu in the lungs where you're more likely to have infections. I would think that this virus is no different."

The plea to quit now

As health officials continue to encourage, publicize, and even mandate measures to slow the spread of the novel coronavirus, doctors stress that unlike risk factors for which there is no cure -- like diabetes, heart disease and older age -- e-cigarette use is behavior that can be modified.

"We should be doing the best we can to manage our health," Dr. Patel implored. "I think the important take-home for teens in the U.S. is this: Even if they are young and healthy, they still play an important part in this."

Doctors say the best time to stop smoking and vaping is now. Along with nicotine patches and gum, prescription medications can help curb cravings and fight addiction. For more information and resources, visit [smokefree.gov](https://www.smokefree.gov).


Chloë E. Nunneley, M.D., a pediatric resident physician at Boston Children's Hospital and Boston Medical Center, is a contributor to the ABC News Medical Unit.

What to know about the coronavirus:

- How it started and how to protect yourself: [**Coronavirus explained**](#)
- What to do if you have symptoms: [**Coronavirus symptoms**](#)
- Tracking the spread in the U.S. and worldwide: [**Coronavirus map**](#)

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Smokers likely to be more at risk from coronavirus: EU agency

 [reuters.com/article/us-health-coronavirus-smoking/smokers-likely-to-be-more-at-risk-from-coronavirus-eu-agency-idUSKBN21C2TS](https://www.reuters.com/article/us-health-coronavirus-smoking/smokers-likely-to-be-more-at-risk-from-coronavirus-eu-agency-idUSKBN21C2TS)

BRUSSELS (Reuters) - Smoking can make people more susceptible to serious complications from a coronavirus infection, the European Union agency for disease control said on Wednesday, citing scientific studies, although available data is still limited.

In its updated assessment of the risks caused by the coronavirus, or SARS-CoV-2, the **European Centre for Disease Control and Prevention (ECDC)** included smokers among those potentially most vulnerable to COVID-19, the disease caused by the virus.

It also said data from China showed 80% of people infected with the disease had only mild symptoms, but in Europe that percentage dropped to 70%, as three in every 10 cases have required hospitalisation.

Patients above 70 years of age and people with underlying conditions such as hypertension, diabetes or cardiovascular disease are among the most vulnerable to COVID-19. Men are more vulnerable than women, the EU body said in its report.

Smokers have also appeared to be more susceptible to breathing complications caused by the disease, and the ECDC said it was advisable to identify them as a potential vulnerable group, confirming an earlier assessment.

The agency cited a study by Chinese doctors which on a sample of 99 patients affected by the coronavirus found that acute smokers were more at risk of dying than elderly people.

The ECDC report also said smoking was associated with heightened activity in the lungs of an enzyme, ACE2, that could make patients more vulnerable to COVID-19, citing a study conducted by Guoshuai Cai, from the University of South Carolina.

The activity of ACE2, or angiotensin converting enzyme 2, also increases with age and with some kinds of hypertension treatment - both risk factors - the ECDC said.

The study, also based on a small sample, concluded that smokers may be more susceptible to the virus.

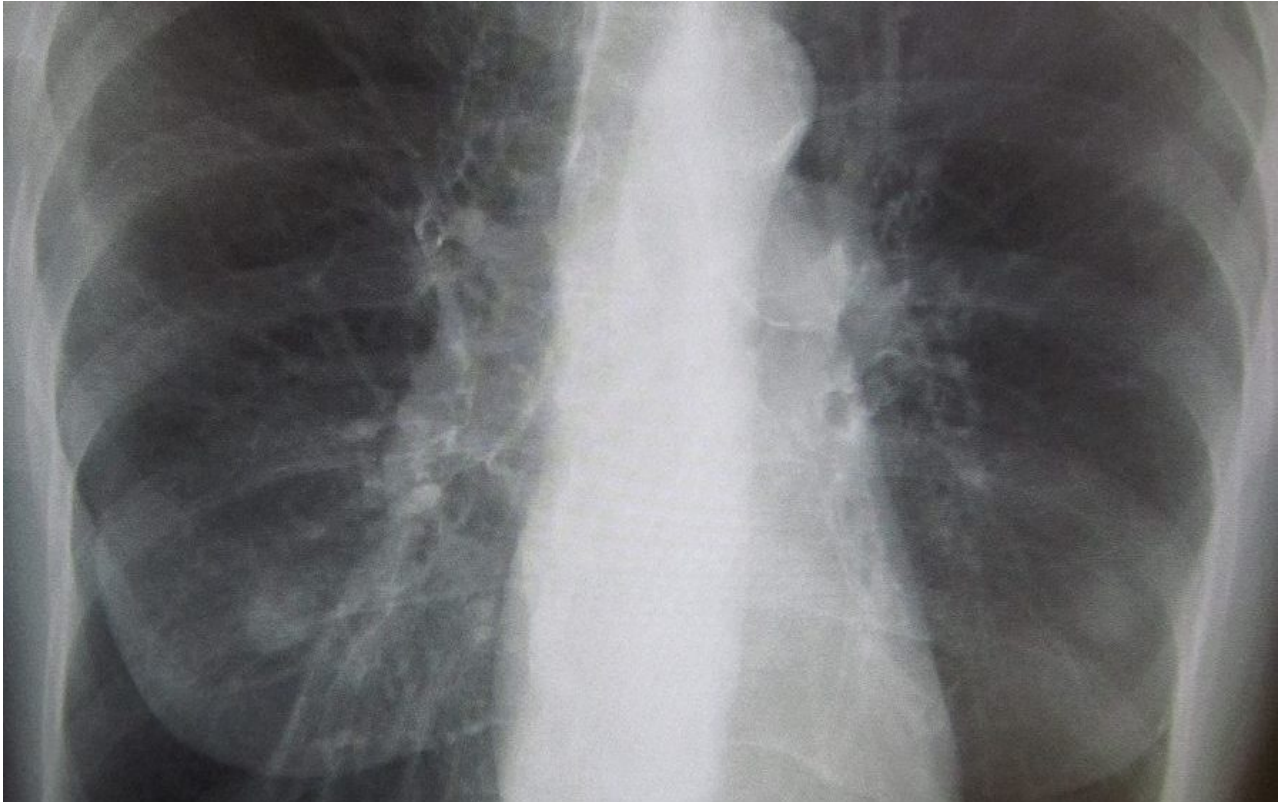
It added that former smokers appeared to be more at risk than current smokers because the enzyme was more active in different cells in former smokers.

Reporting by Francesco Guarascio @fraguarascio and Deena Beasley; Editing by Gareth Jones

Coronavirus: smokers with chronic bronchitis more exposed

[S lasantepublique.fr/coronavirus-fumeurs-bronchite-chronique](https://www.santepublique.fr/coronavirus-fumeurs-bronchite-chronique)

18 mars
2020



As the epidemic linked to the Coronavirus progresses, the profile of the people likely to be most exposed to the effects of the virus is becoming more precise. Among them are people with COPD, a chronic lung disease that affects 700,000 people in France in its most severe form, linked in particular to the harmful effects of tobacco. In the United States, links have even been proven with the new tobacco products that are heating tobacco (Iqos, Glo, Ploom) and electronic cigarettes.

At a time when French tobacco shops remain open in the midst of the Coronavirus crisis, health associations are reminding people of the seriousness of the conditions caused by smoking.

Among the many whistleblowers to have expressed themselves in recent days, the France BPCO association wished to draw attention to an audience particularly at risk : patients with chronic obstructive pulmonary disease. An unknown and not always diagnosed pathology, which results in chronic bronchitis which can lead to progressive obstruction of the respiratory tract. In France, the disease affects 5 to 10% of the adult population, more than half a million people in its severe form. Main cause of this irreversible condition: **smoking.**

As France BPCO reminds us, affected patients " *already suffocate permanently* ". In the event of an influenza epidemic, they are often among the most affected. In view of the medical profile of these first victims, and with all the caution required by the state of scientific research, the Covid 19 seems to accentuate this trend.

The association has split a press alarmist tone to attract the attention of the authorities on this highly sensitive public: " *Arr êtes talking old, children* (almost none are touched, fortunately), *the diabetes, cardiovascular because (...) the Covid 19 destroys the lungs and it is not them either asthmatics who are in danger vital, but the 700,000 COPD stage Sev è re we are and nobody talks* " France BPCO asked the Ministry of Health to raise awareness among hospital services of this patient profile and more protective masks.

Another opportunity to highlight the risks of tobacco

The peak of danger linked to the coronavirus once again highlights the risks run by smokers , even as the forms of harmfulness are diversifying.

The government recently implemented an additional tax tightening on tobacco prices. On March 1, the symbolic price of 10 euros per package was reached for the most consumed brand in France. If such a policy has dissuasive effects, it also has the risk of encouraging smokers to obtain supplies on the black market, while the system for combating illicit trafficking implemented in France is sometimes criticized. Some believe that it is partially under the control of the tobacco industry and that the latter is involved in parallel trade in its products. This policy may also have the consequence of directing consumers towards other products (electronic cigarette, etc.), the lack of which is harmful is seriously questioned by health associations.

Risks for heated and electronic tobacco smokers

The triggering of severe lung diseases in electronic cigarette consumers pushes the scientific community to warn about all of these new products. In the name of the precautionary principle, many experts, including the World Health Organization , recommend that the authorities regulate and tax heated tobacco like conventional cigarettes, *especially* when states are going to need to finance the measures taken to coping with coronavirus shock.

If the harmfulness of heating tobacco like electronic cigarettes is no longer in doubt during normal times, the epidemic of Covid-19 which is raging at present reinforces the fears linked to these products, given the increased respiratory problems of their consumers .

These alerts from the scientific community on the harmfulness of these products come when a study carried out on the Asian market revealed the duplicity of industrialists in the sector. While claiming to develop pseudo-substitutes, the tobacco companies continue to do everything to encourage the consumption of traditional cigarettes.

Recalling that **all forms of smoking are harmful**, the WHO and other public health organizations issue recommendations that make sense in times like the one the world is going through in the age of coronavirus. These recommendations also aim to reduce the risks associated with epidemics, both for potential victims and for severely tested hospital systems.

It seems inevitable that at the end of the current health crisis, comprehensive and harmonized measures to combat all forms of artificial respiratory distress will be taken.

New study reveals duplicity of tobacco companies

 cnct.fr/actualites/une-nouvelle-etude-revele-la-duplicite-des-compagnies-de-tabac

A new study highlights, once again, the large gap between the official, smoothed discourse of tobacco companies and their actual practices. While pushing to promote new cigarettes known as heated tobacco presented as less dangerous, manufacturers continue their aggressive commercial strategy of their conventional cigarettes.

According to a recent report by the Alliance for Tobacco Control in Southeast Asia (SEATCA), "**Tobacco manufacturers have declared and protected more brands of conventional cigarettes than new tobacco or cigarette products electronic.**

In the past four years in Indonesia, Malaysia, the Philippines, Thailand and Vietnam, Philip Morris International (PMI), Japan Tobacco International (JTI) and British American Tobacco (BAT) **have filed 533 registrations to protect their cigarette brands** . Of these, 357 registrations were for traditional cigarette brands compared to 82 for heated tobacco.

Big Tobacco's smoke-free deception:

Tobacco trademarks in ASEAN countries uncover the truth

October 2019



The tobacco industry is thus pushing people to adopt "alternative" tobacco products such as heated tobacco, even as it expands its market for cigarettes. In reality, these new products correspond to another form of cigarettes and are in no way intended to replace other cigarettes but to complement them. Therein lies the hoax of the tobacco manufacturers who say they want to fight the problems caused by their classic cigarettes while continuing to develop the markets.

Trademark registrations pave the way for the formal entry of heated tobacco into the local market, even when prohibited. Although these new products have been banned in Thailand since 2014, 34 applications to register new brands of these products, including IQOS from PMI, have been filed. PMI aggressively promotes its new products and lobbies the government to "offer people a safer alternative".

This tactic offers tobacco companies **an additional opportunity to intervene in local tobacco control laws and policies**. In addition, some applications for registration directly contravene tobacco control law which prohibits misleading descriptors carrying a healthier or less harmful product, such as "Marlboro Zero", "Marlboro Zero Addictive", "Marlboro Silver Less Smell", and "Marlboro Fine Touch Less Smell".

The World Health Organization has explicitly recalled that all forms of smoking are harmful, including heated tobacco, because tobacco is inherently toxic and contains carcinogens, even in its natural form. Currently, WHO says there is no evidence to show that so-called heated tobacco is less harmful. ...

So the tobacco industry has **no intention of reducing sales of its conventional cigarettes while aggressively promoting heated cigarettes**. This allows it to restore its image and put pressure to change protective legislation while increasing its profit margins and expanding its markets. **This study perfectly highlights the imposture of this incredible allegation of tobacco companies adhering to "a smoke-free world"**.

Source: adaptation in French of the [SEATCA report](#)

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About SEATCA (www.seatca.org)

SEATCA is a multi-sectoral non-governmental alliance promoting health and saving lives by supporting ASEAN countries to accelerate and effectively implement the evidence-based tobacco control measures contained in the WHO Framework Convention on Tobacco Control. Acknowledged by governments, academic institutions, and civil society for its advancement of tobacco control in Southeast Asia, the WHO bestowed upon SEATCA the World No Tobacco Day Award in 2004 and the WHO Director-General's Special Recognition Award in 2014. SEATCA is an official NGO Observer to the WHO FCTC Conference of Parties and a co-initiator of the Global Center for Good Governance in Tobacco Control (GGTC).

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Introduction

Big Tobacco's new rhetoric states that cigarettes are harmful and it wants to reduce health risks from smoking. Hence, by selling so-called "less harmful" tobacco products and encouraging smokers to switch to these alternatives,^{1,2,3} it claims that it should be allowed to join the public health community and be a part of the solution to the tobacco epidemic.

Big Tobacco has been aggressively promoting electronic nicotine delivery systems (ENDS), commonly referred to as e-cigarettes, and heated tobacco products (HTP), which both contain nicotine and are addictive. According to the World Health Organization (WHO), all forms of tobacco use are harmful—including HTP—because tobacco is inherently toxic and contains carcinogens even in its natural form. Currently, the WHO states that there is no evidence to demonstrate that ENDS and HTP are less harmful than conventional tobacco products and conclusions cannot yet be drawn about their ability to assist in quitting smoking.^{4,5}

Philip Morris International (PMI) has been especially vocal about going smoke-free. In 2014, PMI started selling its new HTP.⁶ In 2017, PMI announced its vision for a "smoke-free future" and its 12-year funding commitment to set up a Foundation for a Smoke-Free World (FSFW) at USD 960 million (USD 80 million per year) with the purported goal to end smoking.⁷ News of PMI's smoke-free future has been reported in the ASEAN region.^{8,9,10}

brands than for HTP and ENDS (Table 2, Figure 1). This finding demonstrates the duplicity of the tobacco companies' smoke-free rhetoric, as cigarette sales continue to be the core source of revenue of the tobacco industry's business. If tobacco companies were sincere about claiming

Philip Morris International (PMI) has been especially vocal about its smoke-free future, promoting its so-called "less harmful" products as alternatives to cigarettes.

to promote a smoke-free society, they would stop making, marketing, and selling the cigarettes that they now acknowledge as harmful.

Data in the ASEAN region shows that cigarette sales across the countries are increasing (Table 1). A systematic data search was conducted in five ASEAN countries in the database of the government agency responsible for intellectual property (IP) registration¹² to identify trademark registration applications filed by PMI, BAT and JTI for the period January 2015 to April 2019. The data collected was analyzed and supplemented with information on marketing and sales from various sources. This study focuses on brand and

Table 1. Cigarette sales 2016 – 2020 (billion sticks)¹¹

	2016	2017	2018	2019	2020
Indonesia	257.1	264.8	271.5	276.9	281.0
Malaysia	11.5	11.68	11.8	12.0	12.3
Philippines	91.2	92.3	94.0	95.8	97.8
Thailand	50.4	51.0	51.6	52.2	52.7
Vietnam	68.7	70.4	72.5	66.7	68.1

Despite Big Tobacco's smoke-free rhetoric, the reality in ASEAN countries shows that, in these past few years and in at least five ASEAN countries (Indonesia, Malaysia, Philippines, Thailand, and Vietnam), PMI, British American Tobacco (BAT), and Japan Tobacco International (JTI) have been registering many more trademarks for cigarette

pack design registrations for cigarettes, HTP, and ENDS. Trademark applications for individual parts of a whole product were excluded, as were those marked as "other/unidentified tobacco products"; therefore the numbers presented do not reflect the full number of registration applications.

¹ Glossary: 'Registered' and 'registration' refers to trademark applications that are approved. 'Application' refers to still unapproved trademark applications. 'Brand-related' includes both the brand family (e.g. Marlboro) and brand variant (e.g. Marlboro Ice Blast).

Summary of findings

Overall findings

- ▶ **Big tobacco wants smoking to continue.** While tobacco companies publicly claim that cigarettes are harmful, they have simultaneously registered hundreds of trademarks for cigarettes brands and continue to increase cigarette sales. In the five countries, PMI, BAT, and JTI filed 533 IP registrations for cigarette brands, compared to 169 for HTP and ENDS; out of these, 357 cigarette brand registrations were approved compared to 112 for HTP and ENDS (Tables 2 and 3, Figure 1).
- ▶ **PMI filed the most trademark applications for both existing and new cigarette brands.**
 - ▷ 453 brand registration applications in the five countries (compared to 155 by BAT and 94 by JTI); of these, 332 were for cigarettes, 97 for HTP, and 24 for ENDS.
 - ▷ Marlboro brand variants registered: 82 in the Philippines, 29 in Thailand, 19 in Vietnam, and eight in Indonesia.

Country findings

- ▶ **Indonesia** – There were 41 applications for cigarette brands, 6 for HTP, and 8 for ENDS. HTP and ENDS remain unregulated.
- ▶ **Malaysia** – PMI obtained 3 registration approvals for cigarettes, 20 for HTP, and 5 for ENDS. BAT obtained approval for 2 HTP devices and another 4 are still pending. PMI manufactures IQOS in Malaysia for export since 2016. HTP and ENDS remain unregulated.
- ▶ **Philippines** – Cigarettes constituted majority (155) of PMI's 204 trademark registration applications, compared to only 32 for HTP and 17 for ENDS. BAT filed 28 applications (20 for cigarettes), and JTI filed 37 applications (34 for cigarettes). Limited regulations for HTP and ENDS have been set up.
- ▶ **Thailand** – 46 new cigarette brands were registered (27 by PMI, 13 by JTI, and 6 by BAT), while 56 more are still pending registration (43 for PMI, 7 for JTI, and 6 for BAT). Although HTP and ENDS are not allowed for sale, all three companies filed and received approval for HTP brand registrations (19 approved out of 31 filed for PMI, 1 approved out of 2 filed for BAT, and 1 filed and approved for JTI).
- ▶ **Vietnam** – Vietnam had the second highest number (181) of IP registration applications: 178 for cigarettes, 3 for HTP, and none for ENDS. PMI received approval for 46 cigarette brands and 2 for HTP; BAT received approval for 39 cigarette brands and 1 for HTP; and JTI received approval for 4 cigarette brands. HTP and ENDS remain unregulated.

I. Tobacco companies registered more IP under cigarette brands than HTP and ENDS brands

702 applications for intellectual property for various tobacco products were lodged by the three tobacco companies these past four years in the ASEAN region (Table 3). Of these, 459 were successfully registered, while another 215 applications are pending approval.

Despite their public stance about smoke-free and less harmful products, tobacco companies registered in recent years many more trademarks for cigarette brands and variants than HTP

and ENDS. PMI obtained IP approval for 230 cigarette brands; BAT, 72 cigarette brands; and JTI 55 cigarette brands (Table 2); therefore across the region, 76% of all approved trademark registrations were for cigarettes (Figure 1). While governments and the public health community are developing policies and measures to help people reduce tobacco use, tobacco companies have been registering many new brands of tobacco products, largely unnoticed by health ministries and advocates in all the countries.

Table 2. Registered brands for cigarettes, HTP, and ENDS (2015-2019)

Countries	Cigarettes			HTP			ENDS		
	PMI	BAT	JTI	PMI	BAT	JTI	PMI	BAT	JTI
Indonesia	12	9	5	1*	-	-	-	2	-
Malaysia**	3	-	-	20	2	4	5	-	7
Philippines	142	18	33	25	6	-	4	-	2
Thailand	27	6	13	19	1	1	-	-	-
Vietnam	46	39	4	2	1	-	-	-	-
Subtotal	230	72	55	67	10	5	9	2	9
Total	357			82			20		

*Registered in 2014

**IP applications in Malaysia were not primarily for new brands but mainly for devices and packaging.

Figure 1. Trademarks registered for cigarette, HTP and ENDS brands (2015-2019)

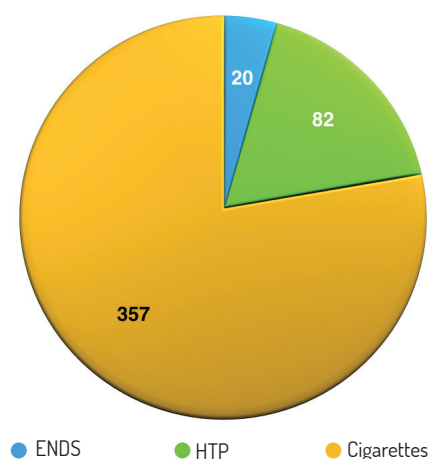


Table 3. Registration status of cigarettes, HTP, and ENDS per company (2015-2019)*

Countries			Indonesia	Myanmar	Philippines	Thailand*	Vietnam	TOTAL		
PMI (n=453)	Approved	C	12	3	142	27	46	230	306	453
		H	1	20	25	19	2	67		
		E	-	5	4	-	-	9		
	Pending	C	2	-	13	43	35	93	138	
		H	3	8	7	12	-	30		
		E	-	2	13	-	-	15		
	Rejected	C	-	-	-	-	9	9	9	
		H	-	-	-	-	-	-		
		E	-	-	-	-	-	-		
BAT (n=155)	Approved	C	9	-	18	6	39	72	84	155
		H	-	2	6	1	1	10		
		E	2	-	-	-	-	2		
	Pending	C	11	-	2	6	21	40	53	
		H	-	4	2	1	-	7		
		E	6	-	-	-	-	6		
	Rejected	C	-	-	-	-	18	18	18	
		H	-	-	-	-	-	-		
		E	-	-	-	-	-	-		
JTI (n=94)	Approved	C	5	-	33	13	4	55	69	94
		H	-	4	-	1	-	5		
		E	-	7	2	-	-	9		
	Pending	C	2	-	1	7	5	15	24	
		H	-	4	-	-	-	4		
		E	2	2	1	-	-	5		
	Rejected	C	-	-	-	-	1	1	1	
		H	-	-	-	-	-	-		
		E	-	-	-	-	-	-		
TOTAL			55	61	269	136	181	702		

*Excludes "other/unidentified tobacco products". C = cigarettes; H = HTP; E = ENDS

Among the five ASEAN countries, the highest number of trademark applications filed by the three tobacco companies was in the Philippines (n=269), with PMI representing 76% (n=204) of all filings and 74% (n=171) of all successful trademark registrations. This is followed by BAT, which holds 10% (n=28) of all filings and 10% (n=24) of successful registrations; and JTI, which holds 14% (n=37) of all filings and 15% (n=35) of all successful registrations. In 2017, BAT closed

its operations in the Philippines, claiming that the country presents a "difficult environment" for the tobacco industry,¹³ it is however still registering its cigarette brands there.

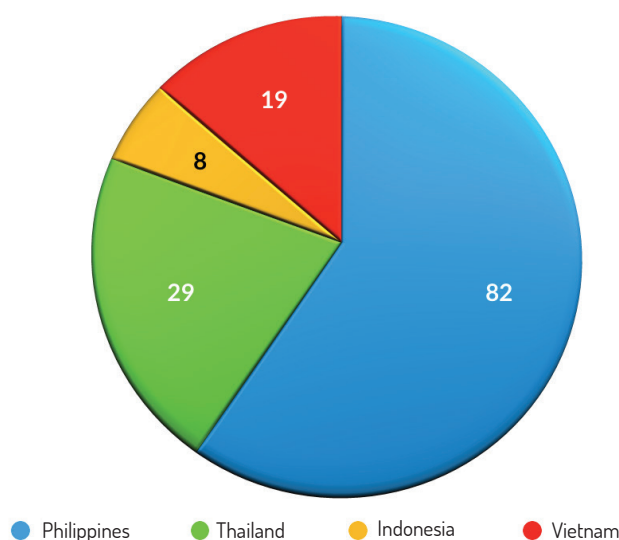
In Vietnam where PMI has only 3% cigarette market share, it received approval for 46 new cigarette brands and 2 HTP (Table 2).

II. PMI registered more cigarette brands than other companies

After launching its so-called less harmful HTP (IQOS) in 2014, PMI promoted it around the world including in the ASEAN region. However, while promoting a 'smoke-free future' and 'less harmful alternatives to cigarettes', PMI was simultaneously registering its cigarette brands. New Marlboro brand variants were registered in Philippines (n=82), Thailand (n=29), Indonesia (n=8), and Vietnam (n=19) (Figure 2).

supporter, to convince the Bali Provincial Government to introduce the concept of risk reduction for cigarettes through alternative tobacco products.¹⁵ However, as shown in Table 2, PMI registered only 1 HTP brand, IQOS, in 2014. HTP and ENDS in Indonesia are more expensive than cigarettes and not as popular.

Figure 2. New Marlboro brand variants registered in five countries (2015-2019)



In Indonesia, of the total 55 applications for new brands these past four years, 41 were for cigarette brands, 6 for HTP, and 8 for ENDS. Those successfully registered included 26 for cigarettes, 12 of which belong to PMI (Table 3).

In Indonesia, PMI is making the bulk of its profits from selling cheap cigarettes. Even while promoting its so-called "less harmful" alternatives, it is simultaneously launching new cigarette brands. For example, in March 2019, PMI launched a new cigarette brand variant with high nicotine and high tar content called Philip Morris Bold, which sells at Rp 12,000 (USD 0.84) for a 12-stick pack (Figure 3).¹⁴

At the same time, the company promoted its HTP, IQOS, with an attempt by the Smoke and Tar-Free Indonesia Coalition (KABAR), an industry

In the Philippines, PMI filed 155 registrations for cigarettes brands and variants from 2015 to 2019 (Table 3). These registrations include cigarette brands manufactured and sold by its local subsidiary, Philip Morris Fortune Tobacco Corporation (PMFTC). Appendix 1 provides details of cigarette, HTP, and ENDS trademark applications per year.

Figure 3. Indonesia: Launch of cigarette brand variant Philip Morris Bold



Left: Billboards advertising new Philip Morris Bold were erected along major roads, 2019. Right: Advertisement promoting new Philip Morris Bold and retail price, 2019. (Photos courtesy of Campaign for Tobacco Free Kids)

Figure 4. Sample of Marlboro brand variants in the Philippines



In 2019, PMI also applied for trademarks for its campaign, “Unsmoke Your World,” in the Philippines, contemporaneous with its “Unsmoke the world”¹⁶ and “Year of Unsmoke” launch.¹⁷ Simultaneously, PMI applied for eight trademarks for Marlboro from January to May, including “Discovered by Marlboro,” “Marlboro Ice Blast

Mega,” “Marlboro Flavor Code,” “Marlboro Gold Legend,” and “Marlboro Red Legend.” In 2018, its HTP-related campaigns, “Delivering Smokers from Smoke” and “This Changes Everything,” were also overshadowed by the trademarks it filed for 20 cigarette products in the same year.

Figure 5. Malaysia: New pack design that conflicts with health warning label requirement

No. PMI 133 was filed on 11 Sep 2017, while PM 153 was filed on 2 Aug 2018.

In 2016 in Malaysia, PMI stated, “We certainly see a future where Philip Morris no longer will be selling cigarettes in the market.”¹⁸ However over these past four years, PMI obtained registration approval for 3 cigarette packaging designs, including a new pack design for its Chesterfield brand that will conflict with pictorial health warning requirements (Figure 5). According to the 2008 Regulations for Control of Tobacco Products (amendment)¹⁹, pictorial health warnings should be placed on the top front and top back panels of cigarette packs.

Since 2016, PMI has manufactured IQOS in Malaysia for export,²⁰ and it has been sold locally both online and in specialized stores since 2018,²¹ although there was no official government announcement as to when PMI was granted permission to sell this new product. While it falls under the definition of tobacco products and is bound by the 2015 Control of Tobacco Products Regulation (amendment),²² it is sold without pictorial health warnings.

BAT Malaysia dominates (57%) the Malaysian cigarette market²³ and, between 2015 and 2019, filed 6 new applications for HTP devices. However, while BAT did not apply for IP registration of any cigarette brand variants and designs, its annual reports²⁴ show that BAT launched new cigarette product or pack designs every year as promotions at points-of-sale, despite the fact that tobacco promotions are banned in Malaysia. It launched 8 cigarette designs in 2015, 4 each in 2016 and 2017, and 6 in 2018, as shown below and in Appendix 2:

- January: Dunhill Limited Edition Pack
- February: Peter Stuyvesant 4Mix (four different flavour capsules in one pack)
- March: Upgraded pack designs for Dunhill’s capsule range
- May: Dunhill Limited Edition Pack
- July: Dunhill Evoque with Malaysia’s first bamboo charcoal filter; Rothmans Kool (menthol range)
- September: Peter Stuyvesant Bamboo Charcoal Filter and Peter Stuyvesant Remix Tropica (“first double novel capsules in one stick”)

Figure 6: BAT’s Peter Stuyvesant cigarette brand promotion

Promotion of Peter Stuyvesant cigarettes at a 7-Eleven outlet in Kuala Lumpur in February 2019.
Photo courtesy of Mary Assunta.

III. Tobacco industry still fights all tobacco control efforts

For years, all around the world, the tobacco industry has fought, delayed, and circumvented government efforts to reduce tobacco use, and its fight against tobacco control has not ceased. This challenge now includes the industry's push for people to embrace the use of alternative tobacco products with weak regulations. In other words, the tobacco industry is expanding its market for both cigarettes and other products such as HTP and ENDS.

Trademark registrations pave the way for the formal entry of HTP and ENDS into the local market, even when they are prohibited. For example, although HTP and ENDS have been banned in Thailand since 2014, there were 34 applications for new trademarks of these products, of which 21 were registered, including IQOS. PMI holds the most trademarks for HTP and ENDS products (74.5%) in the ASEAN region.

Having registered trademarks for HTP and ENDS, tobacco companies then lobby the government and political parties to roll back bans or restrictions on these products. Although the sale of ENDS is illegal in Thailand, the e-cigarette market reportedly has been growing rapidly during the past three years.²⁵

PMI is promoting its new products and applying pressure on the government to "give people a safer alternative."²⁶ Similarly, in Vietnam, the tobacco companies mentioned that the policies maintained by regulators worldwide are barriers to introducing their reduced-risk products.^{27, 28} This tactic provides an additional opportunity for tobacco companies to interfere with local tobacco control laws and policies.

Moreover, some applications filed for registration directly violate the tobacco control law, which prohibits misleading or deceptive descriptors that convey a product is healthier or less harmful, such as "Marlboro Zero" (Philippines), "Marlboro Zero Addictive" and "Marlboro Silver Less Smell" (Thailand), and "Marlboro Fine Touch Less Smell" (Philippines and Thailand). The approval of these unlawful trademarks shows that there is a need to improve coordination between government departments responsible for regulating the tobacco industry and approving trademark applications.

Conclusions

Big Tobacco apparently has no intention to reduce the sales of cigarettes while promoting HTP and ENDS.

In no country has any tobacco company declared a targeted end to cigarette sales. The three transnational tobacco companies—PMI, BAT, and JTI—are increasing cigarette marketing and promoting cigarette sales as reflected in the registration of new cigarette trademarks, despite pushing the rhetoric of the harms of smoking and claimed reduced risk of their new alternative products.

This study exposes the duplicity of tobacco companies' unbelievable claim of going smoke-free.

Recommendations


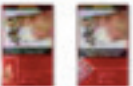

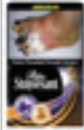

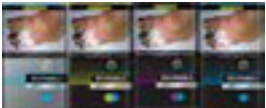














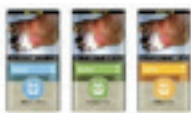



- ▶ Tobacco companies should be exposed for their duplicitous public statements to go “smoke-free,” while they continue to increase cigarette marketing and sales. They should be prohibited from applying trademarks for new cigarette brands.
- ▶ For policy coherence, the IP registration office in each country should notify the Ministry of Health about all tobacco-related IP applications.
- ▶ To be consistent with the goal of reducing and ending tobacco use, applications for new cigarette brands and brand variants should be denied.
- ▶ A more thorough study of new trademarks being registered by tobacco companies on tobacco and related products should be undertaken to assess the industry and help develop policies that can enhance efforts to reduce all forms of tobacco use.

Appendix 1: Philippines: Brand registrations applied per year

		Cig	HTP	ENDS	SL	Brands filed
2019	PMI	3	1	1	0	Marlboro, L&M, Chesterfield, IQOS, VEEV
	BAT	0	1	0	2	GLO, EPOK, LYFT
	JTI	0	1	0	0	PLOOM
2018	PMI	20	2	0	0	Longbeach, Alpine, PhilipMorris, Marlboro, Virginia Slims, Parliament, L&M, Peter Jackson, Fortune, Boss, Stork, Liberty Filters, Miller, Kingston, Diplomat, Captain, Plaza, Green Hill, Ever Green, Westpoint, IQOS, HEETS
	BAT	6	0	0	0	Newport, Silk Cut, Capri, Viceroy, Pall Mall, Kent
	JTI	6	0	2	0	Gold Coast, Winston, Camel, Mevius, Marvels, Mighty, Cores Neo
2017	PMI	11	5	2	0	Marlboro, Philip Morris, Benson & Hedges, Merit, Chesterfield, L&M, Murati Ambassador, Lark, Fortune, Champion, Westpoint, TEEPS, IQOS, CEEGS, EEZE, HEETS, Mesh, Solaris
	BAT	4	2	0	0	Derby, Kool, Pall Mall, Silk Cut, iFUSE, Neo
	JTI	6	0	0	0	Mevius, Winston, Camel, Liggett Ducat, Mighty, American Spirit
2016	PMI	12	3	2	0	Marlboro, Philip Morris, Chesterfield, L&M, Fortune, Choice, More, Bowling Gold, Fortuna, Hope, Jackpot, HEETS, IQOS, TEEPS, STEEM, VEEV
	BAT	2	3	0	0	Pall Mall, Kent, Neo, Glo, Neosticks
	JTI	5	0	0	0	Winston, Caster, Liggett Ducat, American Spirit, Mighty
2015	PMI	23	0	0	0	Philip Morris, Marlboro, Parliament, Virginia Slims, Longbeach, Bond Street, L&M, Chesterfield, Oasis, Lark, True Gold, Fortune, Winter, More, Stork, Liberty Filters, Miller, Diplomat, Captain, Kingston, Green Hill, Ever Green, Plaza
	BAT	11	0	0	0	HB, Capri, Newport, Winfield, Viceroy, Kool, Silk Cut, Pall Mall, SSS Slims, Victory, Senses of Eva
	JTI	11	0	0	0	Camel, Gold Coast, Winston, Mevius, Supercig, L.A., Fate, Texas, Kingsport, Marvels, Frontier

Cig=cigarette, HTP=heated tobacco product, ENDS=electronic nicotine delivery system, SL=smoke-less tobacco (e.g. snuff, snus).

Appendix 2: BAT Malaysia brands launched between 2015 and 2018

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2018			Peter Stuyvesant 4Mix (4 different flavor capsule in one pack) 	DUNHILL Limited Edition Pack (LEP) 				DUNHILL Evoque 		Peter Stuyvesant Remix Tropica 		
	DUNHILL Limited Edition Pack (LEP) 			Upgraded pack for DUNHILL capsule range 			ROTHMANS KOOL (Menthol range) 		Peter Stuyvesant Bamboo Charcoal Filter 			
2017	Peter Stuyvesant Limited Edition Pack 			Dunhill Special Limited Edition 			Dunhill Red Limited Edition Pack 				Introduced ROTHMANS 	
2016	Dunhill Reserved 		Peter Stuyvesant Remix 			Upgraded Dunhill Capsule Range 				Upgraded Dunhill Core Range 		
2015	Dunhill Zest with flavoured capsule 		Pall Mall XL 		Upgraded Peter Stuyvesant 		Dunhill mix featuring two flavoured capsules 			SHUANG XI: new brand 		Peter Stuyvesant Neo 
	Dunhill Core & Menthol range 							Dunhill Red Limited Edition 				
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec

*Compiled by SEATCA based on BATM annual reports

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Heated tobacco products: the example of IQOS

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Heated tobacco products (HTP) represent the latest in a long line of products tobacco companies have developed and marketed as less dangerous than conventional cigarettes, beginning with so-called 'safer cigarettes' in the 1960s.^{1 2} HTP (figure 1) heat tobacco to generate an inhaled nicotine aerosol and are marketed using messages that explicitly or implicitly claim they are safer than cigarettes.^{3–8}

In 2018, HTP were available in many countries (table 1). In the USA, before marketing new tobacco products, the Family Smoking Prevention and Tobacco Control Act⁹ (FSPTCA) requires premarket review by the Food and Drug Administration (FDA) to demonstrate that marketing them would be 'appropriate for the protection of the public health' (FSPTCA sections 910 and 905(j)). Additionally, to market any new tobacco product in the USA with claims of reduced risk or reduced exposure to toxins compared to other tobacco products ('Modified Risk Tobacco Product'; MRTP), the company must first obtain an MRTP marketing order from the FDA. In December 2016, Philip Morris International (PMI) submitted an application to market IQOS, one of its HTP, with MRTP claims.¹⁰ PMI's MRTP application included extensive details about the product, the chemistry of the aerosol it produces, related toxicology, effects on clinical measures in people, perceptions of the product and its packaging (including warning labels), and behavioural factors. This application sought FDA approval of PMI's claims that smokers who switched completely to IQOS would reduce their health risks or exposure to dangerous substances compared with smoking cigarettes.

As of November 2017, there were 31 studies of HTP published in the peer reviewed literature, 20 of which were affiliated with the tobacco industry.¹¹ The 11 independent studies focused on awareness, use, and secondhand emissions of HTP, while the industry affiliated papers examined nicotine delivery and mainstream emissions and exposures to selected toxicants. The fact that the literature has been dominated by industry is particularly concerning because tobacco companies have a record of publishing incomplete or manipulated information and presenting it to governments.^{12–16} For example, PMI^{17–20} and British American Tobacco^{21–23} (BAT) conducted and published studies arguing that additives did not increase cigarettes' toxicities. However, internal PMI documents and analysis of PMI's data done by people independent of the tobacco industry revealed that many toxicants increased when additives—notably menthol—were present.¹⁵

PMI's IQOS MRTP application (the 'application') provides an opportunity to analyse PMI's data. This supplement to *Tobacco Control* includes eight

papers that present analyses of PMI's application by researchers independent of the tobacco industry and 12 papers that provide independent assessments of HTP effects, including their political and policy implications. Together, these papers provide insights into IQOS (and, in broad terms, other HTP) and support the January 2018 vote by the FDA Tobacco Product Scientific Advisory Committee that PMI's application did not demonstrate it reduced risk claims for IQOS²⁴ (online supplementary table S1). These papers also put HTP in the overall context of the tobacco companies' plans to maintain and grow their markets in the future and outline regulatory responses.

HEALTH EFFECTS

The fundamental justification for introducing HTP is the claim that they are substantially less dangerous than conventional cigarettes. PMI's application includes PMI's 3-month study of 24 non-cancer biomarkers of potential harm (BOPH) in humans using IQOS compared with conventional cigarettes. These biomarkers include measures of inflammation, oxidative stress, cholesterol and triglycerides, blood pressure, and lung function. (PMI did separate studies of biomarkers of exposure, several of which are carcinogens.) While PMI's application emphasises that these biomarkers generally changed in positive directions, Glantz's²⁵ examination of the data revealed no statistically detectable difference between IQOS and conventional cigarettes for 23 of the 24 BOPH in Americans and 10 of 13 in Japanese. Moreover, it is likely that the few significant differences were false positives. Thus, despite delivering lower levels of some toxicants, PMI's own data fail to show consistently lower risks of harm in humans using IQOS compared with conventional cigarettes.

In June, 2018 PMI issued a press release²⁶ announcing that a 6-month human study comparing IQOS with conventional cigarettes found eight biomarkers improved in those who switched to IQOS. PMI did not provide specific results. In contrast to the application, PMI's new study only examined six BOPH (plus two biomarkers of exposure). Further, PMI did not report the full range of biomarkers used in the earlier study although they can be measured in a blood sample or simple physiological test. This additional study raises questions about PMI manipulating the experimental design or data analysis as it and other companies have a history of doing.¹⁵

While HTP are presented as 'new', they are simply the latest incarnation of a technology tobacco companies have been developing for decades. Elias *et al*² analysed previously secret PMI documents, public communications and the



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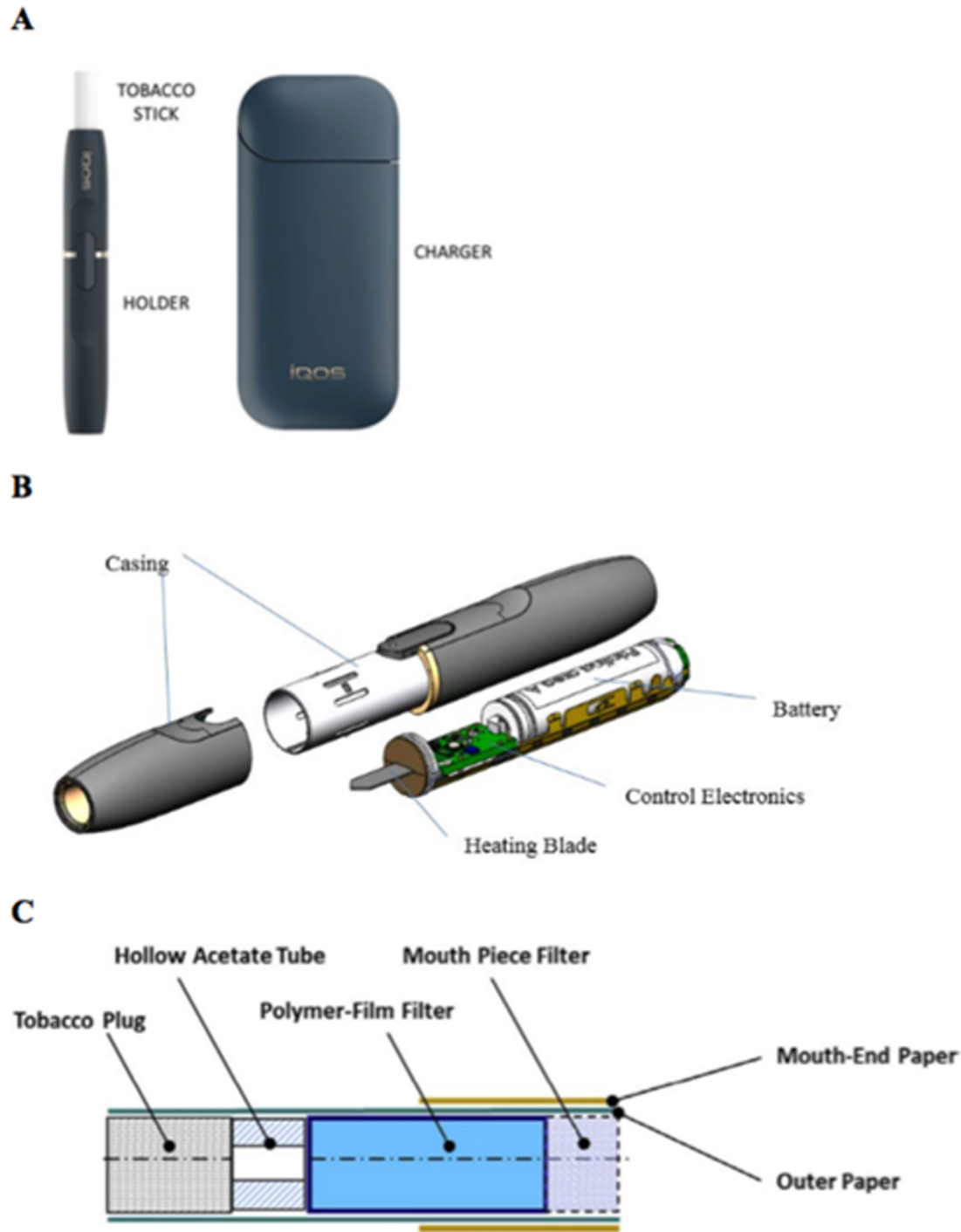


Figure 1 (A) The Philip Morris International IQOS charger, holder and HeetStick (tobacco stick). (B) Schematic drawing of holder. (C) Schematic of HeetStick tobacco stick.¹⁰

application to compare IQOS to Accord, an earlier HTP that PMI unsuccessfully marketed in the USA and Japan in 1998 and 2006, respectively. PMI's public statements seemed contradictory, claiming that Accord reduced exposure to harmful constituents while consistently emphasising that the reductions did not mean Accord was safer than conventional cigarettes. In terms of aerosol chemistry, Accord had lower levels than IQOS of some toxicants and higher levels of others. PMI appears to be capitalising on the MRTP process to make reduced exposure claims for IQOS despite the fact that overall toxicant exposures are not, on average, different than Accord.

Discussion of HTP (as well as e-cigarettes) has focused on cancer even though cardiovascular and metabolic disease kill about as many smokers as cancer.²⁷ Unlike cancer, the dose-response relationship for cardiovascular effects is highly non-linear, with large effects at low doses.²⁸ An important pathway through which tobacco use increases the risk of heart disease is by impairing the ability of arteries to enlarge when needed to accommodate increases in blood flow (flow mediated dilation, FMD). Nabavizadeh *et al*²⁹ tested whether exposure to IQOS aerosol impaired FMD in a well-established experimental model in which rats inhale IQOS aerosol from a single

Table 1 Availability of heated tobacco product by major cigarette company and country of availability (January 2018)

Company	Product	Year launched	Countries/comments
British American Tobacco	iFuse* glo	2015 2016	Romania, Japan, Switzerland, Canada, South Korea, Russia.
China National Tobacco Corporation/State Tobacco Monopoly Administration (STMA)	Not reported	Not launched	A few of the companies claim to have over 30 patents of HTP and continue to be engaged in research and development of these products. But none yet are in the market.
Imperial Brands	Not reported	Not launched	Focusing on e-cigarettes at the moment, claims to have options to launch when it deems that time is right.
Japan Tobacco International	Ploom TECH†	2016	Japan, Switzerland.
KT&G Corp	lii	2017	South Korea
Philip Morris International‡	IQOS TEEPS§	2014 Not yet launched	Canada, Guatemala, Colombia, Czech Republic, Denmark, France, Germany, Greece, Israel, Italy, Kazakhstan, Lithuania, Monaco, Netherlands, Poland, Portugal, Romania, Russia, Serbia, Slovak Republic, Slovenia, Spain, Switzerland, Ukraine, United Kingdom, South Africa, South Korea, Japan, New Zealand.

Source: Bialous and Glantz.⁴⁹

*It is unclear that iFuse will remain in the market in Romania, where glo was introduced in 2018.

†Ploom TECH is described as a hybrid between an HTP and a vapouriser. It is to be used with Mevius capsules. Mevius is one of JTI's best-selling cigarette brands. The capsules contain tobacco that are then heated by vapour.

‡PMI website states that it is developing a new heated nicotine delivery product that has no tobacco, STEEM, among other 'reduced risk' products.

§We do not know what TEEPS stands for, it is not included in the product's description (<https://www.pmi.com/smoke-free-products/teeps-carbon-heated-tobacco-product>).

HTP, heated tobacco product; JTI, Japan Tobacco International; PMI, Philip Morris International.

HeetStick (the IQOS tobacco stick), mainstream smoke from a single Marlboro Red cigarette, or clean air. In contrast with PMI's application claiming that IQOS causes less impairment than conventional cigarettes, Nabavizadeh *et al*²⁹ showed IQOS aerosol's acute effects impaired vascular endothelial function (measured with FMD) comparably with cigarette smoke.

Moazed *et al*³⁰ found data in PMI's application raising significant concerns about IQOS' pulmonary effects. Rats exposed to IQOS suffered pulmonary inflammation and immunomodulation. Although PMI did not report any direct measures of pulmonary inflammation in humans, they measured pulmonary function and found no evidence of improvement in cigarette smokers who switched to IQOS. PMI's application also ignores the effect of dual use and secondhand aerosol exposure.

Independent research confirmed adverse effects of IQOS aerosol on lung cells. Leigh *et al*³¹ exposed human bronchial epithelial cells in vitro to aerosols from three PMI products: IQOS (tobacco flavour), an e-cigarette (MarkTen, tobacco flavour) and a conventional cigarette (Marlboro Red) at comparable nicotine levels at the air-liquid interface. IQOS showed significantly higher cytotoxicity than e-cigarettes, but less than combustible cigarettes. These observations have important legal implications in the USA because to authorise marketing IQOS with reduced risk claims, the FDA would have to find that IQOS would benefit the public health and significantly reduce harm or reduce exposure to harmful substances 'compared to the similar types of tobacco products then on the market' (FSPTCA section 911(g)(2)(B)(ii)), and e-cigarettes were currently on the market at the time that PMI submitted its application.

Reinforcing the need to compare HTP to e-cigarettes rather than cigarettes, Leigh *et al*³² compared the levels of carcinogenic tobacco specific nitrosamines (TSNA) in IQOS aerosols to MarkTen e-cigarettes and Marlboro Red 100 conventional cigarettes at comparable nicotine delivery levels. TSNA yields per puff in IQOS aerosol was an order of magnitude lower than in Marlboro cigarette smoke, but an order of magnitude higher than in MarkTen e-cigarettes. In short, IQOS does not reduce exposure to these important carcinogens nearly as much as e-cigarettes.

Most discussion of the toxicants in non-cigarette tobacco products compare them to cigarettes on the assumption that if the non-cigarette products deliver lower levels of toxicants than cigarettes, the products would be less dangerous. However, St Helen *et al*³³ found that PMI's data only support its claim that IQOS reduces exposure to some (40 of 93) harmful and potentially harmful constituents (HPHCs) identified by the FDA. PMI's data also show significantly higher levels of many toxicants not on the FDA HPHC list in IQOS aerosol compared with cigarette smoke, with 22 over twice as high and 7 over 10 times higher. Therefore, it is important to expand chemical assessment of emissions from HTP and other new tobacco products beyond those found in cigarette smoke.

It is possible that HTP could cause some diseases not caused by conventional cigarettes. Chun *et al*³⁴ identified animal and human studies in PMI's application suggesting that IQOS may cause liver toxicity not observed in cigarette users. PMI compared liver toxicity in rats exposed to IQOS or cigarette smoke, and found that several measures of liver toxicity (liver weights, blood levels of alanine aminotransferase and hepatocellular vacuolisation) increased more in female (but not male) rats exposed to IQOS than cigarettes. PMI's human clinical data also suggested the possibility of increased liver injury in one of their studies: following 5 days of using IQOS, conventional cigarettes, or smoking abstinence, plasma bilirubin was higher in IQOS users than conventional smokers or abstainers. PMI Science posted a response to this paper on its website stating that "based on an analysis of our toxicological studies and clinical studies performed according to international standards of good practice, there is *no evidence* that IQOS use leads to hepatotoxicity [emphasis added]."³⁵ In contrast to this unequivocal statement, the point that Chun *et al* make is not that the data PMI submitted to the FDA prove hepatotoxicity, but that the combination of animal data and some of the human data constitute a pattern worth careful consideration, especially in light of the short duration of the studies and lack of additional potential insults to the liver including alcohol use and other drug use that is common in smokers.

IQOS (and likely HTP generally) are simply *different* from conventional cigarettes and deliver less of some toxicants and more of others, so that IQOS may pose lower, the same or higher health risks than cigarettes depending on the disease. IQOS emits more of several important toxins with more adverse health effects than e-cigarettes.

PERCEPTIONS OF THE PRODUCT AND WARNING LABELS

Despite the evidence discussed above, in 2018 IQOS and other HTP were being marketed around the world with claims that they are less harmful than cigarettes because they expose users to lower levels of some toxicants. Popova *et al*³⁶ examined the qualitative and quantitative Perception and Behavior Assessment Studies in PMI's application which revealed that consumers perceive even reduced exposure claims as reduced risk claims. Allowing PMI to promote IQOS with reduced exposure claims would amount to permitting the kind of 'light' and 'mild' fraud that the FSPTCA and WHO Framework Convention on Tobacco Control (FCTC) expressly prohibit for other tobacco products.

This misunderstanding of reduced exposure as reduced risk bears directly on how IQOS should be labelled so as not to mislead consumers. McKelvey *et al*³⁷ examined PMI's application focusing on the statements that switching completely from cigarettes to IQOS reduces risk. PMI failed to demonstrate that current smokers will understand what 'switching completely' means, and therefore failed to demonstrate that their IQOS will not decrease smokers' intentions to quit smoking, or that IQOS users will 'switch completely' (PMI's other studies showed most people use IQOS and cigarettes concurrently, so-called dual users.) Additionally, PMI's study design and measurement instruments suffered design flaws, and their reporting of associated findings is misleading. Experience with other products such as e-cigarettes suggests consumers will not understand that they must completely quit smoking cigarettes to achieve the claimed health benefits of IQOS. Rather, consumers will likely misunderstand unsupported claims of reduced risks to mean IQOS are risk-free.

Independently confirming PMI's results, El-Toukhy *et al*³⁸ examined the impact of reduced exposure and reduced harm MRTTP claims in a national sample of US adults and adolescents. They found that communicating lower risk in MRTTP claims led to lower perceived risk among adults and adolescents and increased the likelihood that adults would use the product. Reduced exposure claims led to lower perceived chemical quantity and lower perceived risk, but had no effect on likelihood of product use. Adults and adolescents misinterpreted reduced exposure claims as communicating lower risk, even when no explicit reduced risk claims were made. Because reduced exposure MRTTP claims are not permissible under US law if they mislead the public to believe the product presents less risk of harm, these studies demonstrate that reduced exposure claims for IQOS are impermissible.

These concerns are particularly acute for adolescents who are susceptible to using novel tobacco products. E-cigarettes provide a cautionary tale for any new tobacco product coming to market: e-cigarettes have attracted youth at low risk of initiating nicotine use with cigarettes,³⁹ many of whom then proceed to cigarettes.⁴⁰ McKelvey *et al*⁴¹ found that PMI's application failed to provide any evidence regarding the effect IQOS and its marketing will have on the likelihood that adolescents who are not tobacco users or who are former tobacco users will start nicotine use with IQOS. Instead, PMI conducted studies of adults that relied on 'behavioural intention' as a proxy to predict IQOS use, ignoring evidence that these models do not accurately predict tobacco

use. Of added concern, the IQOS name, packaging and retail shops resemble popular cell phones that attract youth.⁴² PMI's data and independent scientific studies regarding novel tobacco products (including e-cigarettes) marketing suggest IQOS will attract adolescent and young adult non-users to initiate tobacco use with IQOS and could also increase polyuse of different tobacco products.

Hair *et al*⁴³ examined IQOS marketing in Japan and Switzerland and studied consumer perceptions, attitudes and behaviours. Expert interviews and IQOS packaging and marketing analyses revealed that IQOS was marketed as a clean, chic and pure product which resonated in cultures that value cleanliness, exclusivity and high-tech appearances. Japanese consumers used IQOS for socialising with non-smokers. Focus group participants in both Japan and Switzerland reported lower levels of satisfaction with IQOS than cigarettes, although many found the packaging appealing. Few participants reported potential health benefits compared with cigarettes.

PMI introduced IQOS to Korea in May 2017. Three months later, Kim *et al*⁴⁴ conducted an online survey of young adults including current, ever and non-users. Rather than switching from conventional cigarettes to IQOS, all current IQOS users continued to use cigarettes or e-cigarettes. There were no IQOS-only users. Current users believed IQOS less harmful or useful to stop smoking. The observation that all the current IQOS users were dual users of conventional cigarettes or e-cigarettes contradicts PMI's assumption that cigarette smokers would switch to HTP.

As of July 2018, the FDA had not authorised HTP for sale in the USA, but awareness and use were increasing. Nyman *et al*⁴⁵ assessed awareness and use of HTP in the USA. From 2016 to 2017, adult awareness of HTP increased from 9.3% to 12.4%, ever use increased from 1.4% to 2.2% and current use doubled from 0.5% to 1.1%. Non-white adults, cigarette smokers, and both current and former users of e-cigarettes were more likely to use HTP.

POLICY, POLITICS AND LAW

Tobacco companies have promoted 'harm reduction' for decades. Although tobacco harm reduction proponents take British psychologist Michael Russell's 1976 idea that 'people smoke for nicotine but they die from the tar'⁴⁶ as an article of faith, he simply presented it as a 'hypothesis'. Elias and Ling⁴⁷ examined tobacco industry documents and found that Russell collaborated with BAT on two 'safer cigarette' studies and received £55 000 (£300 850 or \$398 000 in 2018) to study medium-nicotine low-tar cigarettes. The most prominent early HTP was RJ Reynolds' (RJR) Premier, introduced in the USA in 1988. Russell engaged extensively with RJR about Premier's 'positive aspects' and published an unsigned 1991 *Lancet* editorial⁴⁸ endorsing Premier as a 'near-perfect low tar cigarette' 2 years after RJR stopped marketing Premier without disclosing his conflict of interest. Although Premier failed, RJR saw future business opportunities for novel products if endorsed by health authorities, making conflicts of interest highly important considerations in assessing product endorsements, including those published by high-impact medical journals.

It is important to consider HTP in the context of multinational tobacco companies' product mix and response to the tightening regulatory environment promoted by FCTC. Bialous and Glantz⁴⁹ describe how HTP extend the industry's strategies to undermine government regulation by reframing tobacco companies from part of the problem to part of the solution. Under the 'harm reduction' moniker, companies are attempting

to rehabilitate their reputations to more effectively influence governments to roll back existing tobacco control policies or create exemptions for HTP. Where regulations are absent or loopholes exempt HTP from existing regulations, companies' market HTP to increase social acceptability for all their tobacco products. Governments must ensure that HTP are regulated or banned, and reject partnerships with tobacco companies to promote 'harm reduction'. Doing so requires governments in countries where HTP are not available to keep them out or, if allowed in the market, strictly regulate them under the FCTC.

Israel illustrates how PMI took advantage of regulatory ambiguity to implement an aggressive campaign promoting IQOS as safer than conventional cigarettes. Rosen and Kislev⁵⁰ describe how PMI promoted IQOS as part of its 'Smoke-Free Israel vision' after launching IQOS in December 2016. The campaign began with quiet pre-market meetings with government officials, followed by meetings in Israel's Parliament and an intense campaign in the printed press to promote harm reduction and PMI's 'Smoke-Free Israel vision'. The public campaign included digital and print marketing aimed at young people to promote PMI's 'Smoke-Free Israel vision' and harm reduction using the theme 'IQOS Changes Everything', that stressed IQOS was clean with less smell and no ash. PMI's campaign initially resulted in IQOS' exemption from tobacco regulations. These policies were later reversed after three petitions to the Supreme Court, pressure from health organisations and leading politicians, and wide press coverage of PMI's influence on Parliament's decision-making process. Israel's weak and poorly enforced advertising restrictions, however, have allowed PMI to continue its marketing claims.

In determining whether any new tobacco product may be sold, including HTP, the FDA must consider the product's overall population health impact. Importantly, in addition to any changes in specific toxicity for current smokers who switch from cigarettes to HTP, the availability of HTP affects nicotine and cigarette initiation and cessation. For products that have not been on the market to empirically answer these questions, modelling is an important element of the decision-making process. Max *et al*⁵¹ evaluated PMI's Population Health Impact Model (PHIM), as used in its application, in comparison with other available models. Although similar to many published models, PHIM includes assumptions likely to lead to a positive assessment of IQOS' population health impact. PHIM does not consider impacts on morbidity, underestimates mortality, does not include impacts on non-users, ignores the impact of IQOS on nicotine product initiation among never smokers and does not use the latest US data to set the model's parameters. Because PHIM systematically underestimates the impact of IQOS on the population as a whole, it cannot adequately justify marketing IQOS as 'appropriate to protect public health'.

The most important change in the policy environment since the tobacco companies were last actively promoting HTP in the 1980s and 1990s is the advent of formal regulatory regimes for tobacco products through the FSPTCA in the USA and the FCTC globally. Lempert and Glantz⁵² analysed laws and obligations that apply to the introduction, labelling and marketing of IQOS under FSPTCA and FCTC. PMI's premarket tobacco application and MRTP application for IQOS do not meet FSPTCA requirements on reduced harm or net public health benefit. The FDA can only authorise sale of new products through the new tobacco product pathway that are better for public health than products currently on the market, and e-cigarettes, currently sold in the USA, should probably be the comparator product. FCTC obligates parties to implement laws to reduce tobacco use

and nicotine addiction, and the introduction of any new tobacco product must be assessed against this goal. PMI's aggressive marketing techniques for IQOS using targeted customer interventions and sophisticated technologies to capture data and monitor use directly from the IQOS device via the internet⁵³ should concern privacy and public health advocates. Moreover, nothing in the US law or FCTC prevents authorities from prohibiting HTP. If not banned, all HTP components should be regulated as stringently as tobacco products, including restrictions on labelling, advertising, sales to minors, price and taxation policies, and smoke-free measures, and these laws should be aggressively enforced.

CONCLUSION

HTP 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. IQOS and other HTP are the newest in a long string of products designed to retain customers and protect tobacco companies' reputations and political influence. Because US law required PMI to provide detailed results of their IQOS research for its MRTP application, it was possible to independently assess their research. **PMI's own data do not support its claims that IQOS is less dangerous than cigarettes.** While IQOS may expose users to lower levels of some toxicants than cigarettes, they also expose users to higher levels of other toxicants. Likewise, IQOS likely exposes users to lower risks of some diseases and higher risks of others. PMI's research, confirmed by independent research, also highlights the fact that reduced exposure claims are misunderstood as reduced harm claims. These facts raise serious concerns that HTP and their marketing will harm youth and young adults and undermine cessation among smokers without providing health benefits to smokers who use them.

Fortunately, regulatory tools are in place to make rational, evidence-based decisions about these products. The question is whether public health advocates will ensure that policy-makers prioritise protecting public health and prevent tobacco companies from again using their extensive public relations and political resources to avoid regulation and protect profits. Policy makers should give greater weight to the advice provided by public health scientists than to submissions from industry when it comes to regulating tobacco products such as HTP.

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