

June 27, 2024

Dr. Brian King
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Sent by e-mail

Dear Dr. King:

As you are aware, within the last several years, the U.S. Food and Drug Administration (FDA) has granted various marketing granted orders (MGOs) and modified risk orders (MROs) to affiliates of Philip Morris International (PMI and its affiliates hereinafter referred to as PMI) for its IQOS heated tobacco system and its Heatstick components (hereinafter referred to as IQOS). PMI now has applied for renewal of its “exposure modification order” for IQOS 3,¹ as well as filing for premarket authorization of ILUMA, its next-generation IQOS product, and for a modified exposure order for ILUMA that seeks to make the same “reduced exposure” claim it was authorized to make for IQOS 3. We write to ensure that FDA consider various developments since these orders were granted for IQOS that bear on whether the previously granted modified exposure orders should be renewed and whether the marketing order and modified exposure applications for ILUMA should be granted. Those developments fall into three categories:

- (1) Recent independent studies of IQOS in other countries fail to show a population-wide public health benefit;
- (2) PMI repeatedly has made misleading and deceptive statements wrongly suggesting that FDA has found that IQOS reduces the risk of disease; and
- (3) FDA’s own conclusions supporting a prohibition of menthol cigarettes contradict any justification for continued or future authorization of menthol-flavored IQOS.

Background

Following the grant of the MGO on April 30, 2019, Altria, the exclusive distributor of IQOS in the United States, began selling IQOS in September 2019 in Atlanta, GA, before expanding its sales to Richmond, VA in November 2019 and to Charlotte, NC in July 2020. By late 2021, IQOS and Heatsticks were available throughout Georgia, Virginia, North Carolina, and

¹ Under Section 911 of the FDCA, such exposure modification orders are a type of “modified risk” order. *See* 21 U.S.C §387k(b)(1) and (2)(A)(i).

South Carolina.² However, in September 2021, the U.S. International Trade Commission ruled against PMI in a patent infringement action brought by British American Tobacco and imposed a ban on imports of IQOS into the U.S.³ Altria announced that it would stop selling IQOS and Heatsticks in the U.S. on November 29, 2021⁴ and, in January 2022, the company announced that it did “not expect to have access to IQOS devices or Marlboro Heatsticks in 2022.”⁵ Thus, IQOS was available in the U.S. for approximately two years (2019-2021). PMI has announced that it plans to reintroduce early versions of IQOS in four cities in two states in the second quarter of 2024, using the distribution system of Swedish Match, its newly acquired subsidiary.⁶ In July 2023, PMI filed for renewal of its “exposure modification order” for IQOS 3.⁷

In October 2023, PMI filed for premarket authorization of ILUMA, its next-generation IQOS product, and also filed a modified risk application for ILUMA that seeks to make the same “reduced exposure” claim it was authorized to make for IQOS 2.4 and 3. The company has stated it plans a national roll-out of ILUMA following the grant of a marketing order, reaching ten states in the first year, and using the distribution system of Swedish Match.⁸

Various public health organizations have submitted multiple filings with FDA opposing the marketing and modified risk orders granted to PMI for its IQOS products on several grounds,⁹ including the following:

² Campaign for Tobacco-Free Kids (Tobacco-Free Kids), *Heated Tobacco Products: Philip Morris International’s IQOS*, at 2 (Mar. 28, 2022), <https://assets.tobaccofreekids.org/factsheets/0404.pdf>.

³ *Certain Tobacco Heating Articles & Components Thereof*, Inv. No. 337-TA-1199, Notice of the Commission’s Final Determination Finding A Violation of Section 337; Issuance of a Limited Exclusion Order and Cease and Desist Orders; Termination of the Investigation, 2021 WL 4520945 (U.S. Int’l Trade Comm’n Sep. 29, 2021).

⁴ Altria, *IQOS and the ITC Decision*, Dec. 31, 2021 archive accessed from Wayback Machine, <https://web.archive.org/web/20211231035553/https://www.altria.com/about-altria/our-voice-and-actions/iqos-and-the-itc-decision>.

⁵ Seeking Alpha, Altria Group, Inc. (MO) CEO Billy Gifford on Q4 2021 Results - Earnings Call Transcript (Jan. 27, 2022), <https://seekingalpha.com/article/4482171-altria-group-inc-mo-ceo-billy-gifford-on-q4-2021-results-earnings-call-transcript>.

⁶ PMI, Philip Morris International’s 2023 Investor Day Transcript, at 68 (Sep. 28, 2023), <https://philipmorrisinternational.gcs-web.com/static-files/539f900e-e06e-469d-8851-934a5c0bf334>.

⁷ *Id.* at 51.

⁸ *Id.* at 68.

⁹ The undersigned here incorporate those filings by reference. *See* Comments of Tobacco-Free Kids to TPSAC, Docket No. FDA-2017-N-5994 (January 3, 2018), https://assets.tobaccofreekids.org/images/content/2018_01_03_CTFK_IQOS_comments.pdf; Letter from Matthew Myers to CTP Director Mitch Zeller re Global Marketing of IQOS by PMI (March 23, 2018), https://assets.tobaccofreekids.org/press_office/2018/2018_03_28_IQOS_global_marketing.pdf; Letter from Matthew Myers to CTP Director Mitch Zeller re Social Media Marketing of IQOS in the United States by PMI (August 13, 2018), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2018_08_13_IQOS_FDA_Social_Media_Marketing.pdf; Comments of Public Health Groups in Docket No. FDA-2017-D-3001 (February 11, 2019), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/2019_02_11_Public_Health_Groups_Comments_IQOS_MRPTAs.pdf; Letter of Public Health Groups to CTP Director Mitch Zeller re Marketing Order for IQOS (May 14, 2019), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2019_05_14_youth_marketing_iqos.pdf; Comments of Public Health Groups in Docket No. FDA-2021-N-0408 (December 10, 2021), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/2021_12_10_IQOS-3-MRTPA-Comments.pdf.

- PMI presented insufficient evidence on the impact of the marketing of IQOS with modified risk claims on non-users of tobacco products, including youth.
- PMI presented insufficient evidence that its marketing will target only adult smokers, particularly in light of its marketing of IQOS abroad, which reaches youth, and its social media marketing,¹⁰ which reached youth in the U.S. prior to the issuance of a marketing order.
- PMI did not provide information on the impact of marketing menthol IQOS products with modified risk claims on the Black population and youth.
- The evidence indicates that the marketing of IQOS with modified risk claims will lead to greater dual use with cigarettes instead of leading substantial numbers of smokers to switch completely to IQOS.
- There is substantial scientific uncertainty about the extent of individual health benefits from complete switching from cigarettes to IQOS.

New Developments Bearing on IQOS Marketing and Modified Risk Orders

New developments since the issuance of the marketing and modified risk orders for IQOS indicate that the reintroduction of the IQOS products as modified risk products, and the marketing of ILUMA as a modified risk product, will fail to meet the “appropriate for the protection of the public health” statutory standard. First, recent independent studies of IQOS in other countries fail to identify any population-wide benefit from this product. Second, PMI has shown that if its reduced exposure claims are permitted, the company will convert FDA’s authorization into claims that IQOS products are reduced risk products. After FDA authorized specific reduced exposure statements in July, 2020, PMI officials repeatedly made misleading and deceptive public statements suggesting that the FDA found IQOS to be less harmful or to present less of a risk of disease than one or more other tobacco products, when FDA has found the evidence insufficient to establish a lower risk of disease from IQOS. Third, FDA’s own conclusions supporting a rule prohibiting menthol cigarettes undercut any justification for the authorization of menthol-flavored IQOS.

I. RECENT INDEPENDENT STUDIES OF IQOS IN OTHER COUNTRIES FAIL TO SHOW A POPULATION-WIDE PUBLIC HEALTH BENEFIT

Recent research on the impact of IQOS in other countries fails to demonstrate a public health benefit from the introduction of IQOS, indicating that marketing and modified risk orders sought by PMI may not be appropriate for the protection of public health.

In January 2022, Cochrane Library issued *Heated tobacco products for smoking cessation and reducing smoking prevalence*, reviewing the available studies of these products, of which the majority were produced by tobacco companies and were determined by Cochrane reviewers to be at unclear or high risk of bias. The review concluded, “No studies reported on the

¹⁰ PMI’s global social media marketing of IQOS is discussed in Tobacco Free Kids’ Report *#SponsoredByBigTobacco: Tobacco & Nicotine Marketing on Social Media* (Dec. 2023). https://assets.tobaccofreekids.org/content/what_we_do/industry_watch/social-media-marketing-tactics/2023_12_08_SponsoredByBigTobacco.pdf.

use of heated tobacco for cigarette smoking cessation, so their effectiveness for this purpose remains uncertain.”¹¹

Because PMI first introduced IQOS in Japan in 2014, it often points to that country as a model example of its success, showing high rates of “conversion” from cigarettes to IQOS and declines in cigarette sales paired with increases in IQOS sales.¹² Importantly, Japan regulates tobacco products very differently from the U.S.; for instance, nicotine e-cigarettes can only be sold in Japan if they have received approval as medicinal products, and no such products have been approved.¹³ In Japan, therefore, e-cigarettes do not compete in a legal market with heated tobacco products (HTPs). As the Cochrane Library report commented about the experience in Japan, “The rate of decline in cigarette sales accelerated after the introduction of heated tobacco to market in Japan but, as data were observational, it is possible other factors caused these changes. Moreover, falls in cigarette sales may not translate to declining smoking prevalence, and changes in Japan may not generalize elsewhere.”¹⁴ For comparison, an analysis of sales data in Poland, where both e-cigarettes and HTPs are available, showed that HTP sales added to the steady conventional cigarette sales,¹⁵ rather than coinciding with a decline in those sales.

Analysis of data from the International Tobacco Control Policy Evaluation Project (ITC Project), presented in a session at the 2023 Society for Research on Nicotine and Tobacco Annual Conference, showed not only that PMI’s claims about complete switching rates in Japan are inaccurate, but that most smokers become dual users and actually increase their overall tobacco consumption as a result. Gravely, et al., found that only 17% of IQOS users had “completely transitioned” to IQOS in 2020, compared to the 73% that PMI claimed in its Shareholder report.¹⁶

Fong, et al.,¹⁷ found a higher likelihood of transitioning from exclusive smoking to long-term dual use of cigarettes and HTPs compared to transitioning to exclusive HTP use. They did not find an association between long-term HTP use and greater likelihood of quitting cigarettes. Finally, they determined that smokers who had ever used HTPs were less likely to quit all tobacco compared to those who had never used HTPs. The researchers concluded, “The dramatic

¹¹ Harry Tattan-Birch et al., *Heated tobacco products for smoking cessation and reducing smoking prevalence*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS, Issue 1. Art. No.: CD013790, at 21 (2022), <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013790.pub2/epdf/full>.

¹² See, e.g., PMI, *Can innovative products like IQOS accelerate the decline of smoking?* (last accessed Dec. 13, 2023), <https://www.pmi.com/sustainability/case-studies-and-market-stories/can-innovative-products-like-iqos-accelerate-the-decline-of-smoking>.

¹³ <https://globaltobaccocontrol.org/en/policy-scan/e-cigarettes/countries?country=101>.

¹⁴ Tattan-Birch et al., *supra* at 11.

¹⁵ Alex C. Liber et al., *Poland is not replicating the HTP experience in Japan: a cautionary note*, 32 TOBACCO CONTROL 524 (2023), <https://pubmed.ncbi.nlm.nih.gov/34876532/>.

¹⁶ The analysis was conducted using PMI’s characterization of “completely transitioned,” defined as at least 95% of respondents’ total tobacco consumption coming from HTPs. Gravely, S, et al. An Examination of Philip Morris International’s Estimate of IQOS Consumers Who Have “Completely Transitioned” From Cigarettes: Findings From the 2018/19 and 2020 ITC Japan Surveys. Presentation at 2023 Society for Research on Nicotine and Tobacco Annual Meeting. March 3, 2023 (attached as Exhibit 1).

¹⁷ Fong, GT, et al. Transitions of Tobacco Product Use Among Adults Who Smoke Cigarettes and Adults Who Use Heated Tobacco Products (HTPs) in Japan: Initial Findings from Three Waves of the ITC Japan Cohort Survey (2018-20). Presentation at 2023 Society for Research on Nicotine and Tobacco Annual Meeting. March 3, 2023 (attached as Exhibit 2).

decrease in cigarette sales and the increase in HTP sales in Japan is likely due (nearly) entirely to partial substitution among smokers who are now duals, and likely to become long-term duals rather than due to smokers quitting or transitioning to using neither product.”

In looking at cigarette and HTP stick consumption among those who transitioned between various stages of use in Japan, Xu, et al.,¹⁸ found that dual users added more HTP sticks than they reduced cigarettes, resulting in an increase in overall tobacco consumption. Along with those from a small preliminary study, where switchers had higher IQOS consumption,¹⁹ these findings may indicate a possible new pattern of use about which the health consequences are unknown. Even if IQOS or HTPs provide lower exposure to toxicants than cigarette smoking, if consumption is higher, this may not translate into a reduction of a user’s risk.

The ITC Project’s data from South Korea, presented at the 2024 Society for Research on Nicotine and Tobacco Annual Conference, showed similar results to those for Japan. Analysis found substantially lower rates of complete switching among cigarette and IQOS users, indicating that PMI exaggerated its claims of switching.²⁰ A separate study found high rates of dual use among cigarette smokers who took up HTPs and very low rates of complete switching among cigarette smokers, leading to the conclusion that “HTP use was not associated with smoking cessation but with a very high percentage of HTP-cigarette dual use (>95%).”²¹ A third study found increases in total tobacco consumption among dual users, due to added HTP stick use that outweighed the slight reduction in cigarettes smoked.²² Of note, South Korea allows the sale of e-cigarettes, like in the U.S., but in the ITC Project’s analysis, e-cigarette use did not have a measurable impact on the results.

Thus, analyses of the IQOS experiences in Japan and South Korea demonstrate that dual use is the most common use pattern, leads to increased tobacco consumption, and tends to be long-term and not associated with complete quitting of all tobacco products. The available independent research, therefore, does not indicate that IQOS produces any real benefits for individual or population health.

¹⁸ Xu, SS, et al. Changes in Cigarette and Total Tobacco Consumption Among People Who Smoke Who Did and Did Not Initiate Heated Tobacco Products: Findings from the 2018-2021 ITC Japan Surveys. Presentation at 2023 Society for Research on Nicotine and Tobacco Annual Meeting. March 3, 2023 (attached as Exhibit 3).

¹⁹ Matthew D. Stone et al., *Switching from cigarettes to IQOS: A pilot examination of IQOS-associated reward, reinforcement, and abstinence relief*, 238 DRUG & ALCOHOL DEPENDENCE (2022), <https://www.sciencedirect.com/science/article/abs/pii/S0376871622003064?via%3Dihub>.

²⁰ Gravely, S, et al. An Examination of Philip Morris International’s Estimate of Korean Adults Who Have “Completely Transitioned” from Cigarettes to IQOS: Findings from the 2020 and 2021 ITC Korea Surveys. Presentation at 2024 Society for Research on Nicotine and Tobacco Annual Meeting. March 23, 2024 (attached as Exhibit 4).

²¹ The study found that only 0.3% of exclusive cigarette smokers transitioned to exclusive HTP use. Fong, GT, et al. Transitions between Cigarettes and Heated Tobacco Products among Adults Who Use Vs Do Not Use Nicotine Vaping Products in the Republic of Korea: Findings from the 2020, 2021, and 2023 ITC Korea Surveys. Poster Presentation at 2024 Society for Research on Nicotine and Tobacco Annual Meeting. March 22, 2024 (attached as Exhibit 5).

²² Xu, SS, et al. Changes in Total Tobacco Consumption among Korean Adults When Transitioning Between Exclusive Cigarette Smoking and Dual Use of Cigarette and Heated Tobacco Products: Findings from the 2020-2023 ITC Korea Surveys. Presentation at 2024 Society for Research on Nicotine and Tobacco Annual Meeting. March 23, 2024 (attached as Exhibit 6).

II. PMI REPEATEDLY HAS MADE MISLEADING AND DECEPTIVE STATEMENTS WRONGLY SUGGESTING THAT FDA HAS FOUND THAT IQOS REDUCES THE RISK OF DISEASE

The MGO granted for IQOS 2.4 in 2019 was followed by the grant of PMI's modified risk application on July 7, 2020. It is critical to understand that PMI's application sought to make two kinds of modified risk claims in marketing IQOS: (1) under Section 911(g)(1) of the FDCA, a "reduced risk" claim that switching completely from conventional cigarettes to IQOS "can reduce the risks of tobacco-related diseases," and (2) under Section 911(g)(2)(A) and (B), a "reduced exposure" claim that switching completely from conventional cigarettes to IQOS "significantly reduces your body's exposure to harmful or potentially harmful chemicals."

FDA denied PMI's request for authorization to make a "reduced risk" claim (a "risk modification order") because the Technical Project Lead Scientific Review (TPL)²³ found that "the applicant **has not demonstrated** that, as actually used by consumers, the products sold or distributed with the proposed modified risk information will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products." TPL at 8 (emphasis in original). FDA issued only an "exposure modification order," authorizing only the following "reduced exposure" claim:

AVAILABLE EVIDENCE TO DATE:

- The IQOS system heats tobacco but does not burn it.
- This significantly reduces the production of harmful and potentially harmful chemicals.
- Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.²⁴

The July 7 exposure modification order specifically instructs PMI that "because these products have not been authorized under section 911(g)(1) (risk modification order) you may not market these products with reduced risk claims." In addition, FDA stated that it would monitor PMI's marketing of the product.²⁵

The importance of this instruction to PMI follows from the provisions of the FDCA governing modified risk applications. The authorization to make "reduced exposure" claims under Section 911(g)(2) requires companies to refrain from marketing the authorized tobacco product as a reduced risk product under Section 911(g)(1). Moreover, the authorization to make "reduced exposure" claims requires a showing that:

²³ <https://www.fda.gov/media/139796/download?attachment>.

²⁴ Modified Risk Granted Orders – Exposure Modification, at 1 (July 7, 2020), <https://www.fda.gov/media/139797/download?attachment>.

²⁵ *Id.* at 2 (emphasis in original).

(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product –

- (I) Is or has been demonstrated to be less harmful; or
- (II) Presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products.²⁶

Thus, the July 7 exposure modification order limited the statements that PMI could make so that consumers will not be misled by the “reduced exposure” claims into believing that IQOS had been demonstrated to be less harmful or to reduce the risk of tobacco-related disease. The World Health Organization (WHO), after the FDA order was issued, warned against misleading representations of the FDA action, noting that “[t]he US FDA authorization rejected claims that the use of the product is less harmful than another tobacco product or reduces risks to health,” and “[t]he exposure modification orders . . . do not permit the company to make any other modified risk claims”²⁷

Statements made by PMI about IQOS since FDA authorized the “reduced exposure” claim have been calculated to associate IQOS with a reduction in disease risk, in violation of the statute and FDA’s instruction to PMI to avoid reduced risk claims. For example, on the day FDA authorized the marketing of IQOS with a “reduced exposure” message, a PMI press release repeatedly referred to IQOS as a “better choice” for smokers than continuing to smoke:

- “Today’s decision demonstrates that IQOS is a fundamentally different tobacco product and a better choice for adults who would otherwise continue smoking.”
- “The FDA’s decision further builds on the emerging independent international scientific consensus that IQOS is a better choice than continuing to smoke”
- “Today’s decision makes it possible to inform these adults that switching completely to IQOS is a better choice than continuing to smoke.”²⁸

Other statements in the press release provide added context, making it clear that the phrase “better choice” is meant to convey that IQOS is a healthier choice that reduces the risk of disease:

- “The best choice **for health** is to never start smoking or to quit altogether. For those who don’t quit, the best thing they can do is switch to a scientifically substantiated smoke-free product.” (emphasis added)²⁹

²⁶ Section 911(g)(2)(B)(iii) of the Tobacco Control Act.

²⁷ WHO statement on heated tobacco products and the US FDA decision regarding IQOS (July 27, 2020) (WHO statement) <https://www.who.int/news/item/27-07-2020-who-statement-on-heated-tobacco-products-and-the-us-fda-decision-regarding-iqos>.

²⁸ PMI, *FDA Authorizes Marketing of IQOS as a Modified Risk Tobacco Product* (July 7, 2020) (statement by PMI CEO Andre Calantzopoulos), <https://www.pmi.com/media-center/press-releases/press-details/?newsId=22631>.

²⁹ This identical statement also was posted on the PMI website. See PMI, *U.S. FDA authorizes PMI’s IQOS as a modified risk tobacco product (MRTP)* (July 7, 2020) <https://www.pmi.com/media-center/news/fda-authorizes-pmi-iqos-as-modified-risk-tobacco-product>.

- “PMI is building a future on a new category of smoke-free products that, while not risk-free, are a much better choice than continuing to smoke.”

These statements from PMI convey the message that switching from conventional cigarettes to IQOS is a “better choice” because IQOS reduces the risk of harmful health effects. This is precisely the kind of “reduced risk” claim that PMI was instructed by FDA not to make in its marketing of IQOS because the science does not support such a claim.

PMI repeatedly has made similar “reduced risk” statements to support its efforts to use the FDA exposure modification order to promote IQOS globally and, particularly, to lobby foreign governments to create a legislative and regulatory environment favorable to IQOS:

- In September of 2020 during a webinar in the Philippines, Stacey Kennedy of PMI Asia Pacific operations, said, “**IQOS, our leading flagship brand in the reduced risk portfolio, was granted the modified risk tobacco claim in the United States.**” According to a news article covering the webinar, Ms. Kennedy also “explained [that] the US FDA decision has effectively differentiated IQOS from combustible products **when it comes to health risk.**”³⁰
- An ad in Mexico mentions that IQOS has “been authorized by the U.S. Food and Drug Administration (FDA) as a product of ‘modified risk’” and then later includes a quote from a PMI official that PMI wants to inform smokers “about the **lower risk alternatives**” that exist in Mexico.³¹
- In an April 2022 letter to the Prime Minister of Kazakhstan referencing the FDA modified risk order, PMI threatened to pull back investments in Kazakhstan if the country didn’t share “the same views on the **reduced risk potential** of our next generation products and an appropriate regulatory framework.”³²

Thus, PMI has repeatedly misrepresented its FDA exposure modification order—in violation of that order—to create a favorable environment for the sale of IQOS in multiple countries.

In evaluating these misleading statements, FDA should recognize that the term “modified risk tobacco product” in the TCA is not limited to products with claims of reduced risk made in advertising for the product. Rather, the term is broadly defined to include a tobacco product “the manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product’s label, labeling or advertising . . . that would be reasonably expected to result in consumers believing that the tobacco product . . . may present a lower risk of disease . . . or presents a reduced exposure to . . . a substance or substances.”³³ The PMI statements quoted above, in press releases, webinars, advertisements and

³⁰ <https://mb.com.ph/2020/09/07/philip-morris-urges-ph-to-adopt-us-fda-finding/> (September 7, 2020) (emphasis added).

³¹ <https://lifeandstyle.expansion.mx/bspoke-ad/2021/08/19/iqos-y-el-proceso-de-cambio-para-evolucionar> (June 21, 2021) (emphasis added) (certified English translation attached as Exhibit 7).

³² Exhibit 8, at 1 (emphasis added).

³³ 21 U.S.C. §387k(b)(2)(A)(iii).

letters to public officials and legislative bodies, arguably are, either directly or indirectly, directed at consumers and can be expected to result in consumer misunderstanding of what FDA actually found. These types of promotional statements still fall within FDA's obligation to monitor PMI's marketing of IQOS, even if they are not advertising in the traditional sense.

Nor should the fact that some of the statements were made in other countries render them irrelevant to FDA's evaluation of whether PMI's pending applications should be granted. First, nothing in the TCA limits the restrictions on modified risk claims to statements made in the United States. Second, FDA has a strong interest in protecting the integrity of its orders against misrepresentation wherever it occurs. The TCA permits certain claims to be made about products in order to facilitate the communication of truthful information to consumers, not the communication of false or misleading information designed to promote the product in foreign markets. Third, in this online age, it is fanciful to imagine that the impact of a misleading statement about a product made in another country will be limited to that country, with no effect on U.S. consumers. Indeed, the notion that a statement has a single "location" has become an anachronism. For instance, as mentioned previously, PMI's paid social media marketing for IQOS from other countries still reaches young audiences in the U.S. Finally, the fact that PMI repeatedly has misrepresented the FDA orders suggests a serious risk that it will do so again in connection with any newly authorized IQOS products and claims in the U.S.

PMI's misuse of the FDA exposure modification order is particularly concerning because it exploits, and likely exacerbates, the tendency of consumers to interpret reduced exposure claims as indicating reduced risk. One recent study examined the impact of IQOS advertising with reduced exposure versus reduced risk messaging among 2,222 US and Israeli adults.³⁴ It found that reduced exposure (vs. control) messaging resulted in lower perceived relative harm, exposure and disease risk. According to the study, "These results suggest that consumers do not clearly disentangle the differences in the reduced risk versus reduced exposure messaging, as noted in prior research."³⁵ The authors cite prior research showing that "[m]any consumers misinterpret the authorized IQOS messaging regarding reduced exposure claims as indicating reduced risk."³⁶ They also note that since July 2020, media reports in several countries cite PMI as "mischaracterizing FDA's MRTP decision as evidence that IQOS is a reduced harm product . . ."³⁷ In sum, "Current findings show that participants do not adequately distinguish between reduced exposure and reduced risk language – therefore not meeting the criteria for using this language in IQOS marketing – and that [PMI] further exploits this potential to unduly influence consumers by misrepresenting FDA authorization in other countries."³⁸

³⁴ Carla J. Berg et al., *Impact of FDA endorsement and modified risk versus exposure messaging in IQOS ads: a randomized factorial experiment among US and Israeli adults*, TOBACCO CONTROL (published online ahead of print, 2022 Nov. 25), <https://tobaccocontrol.bmj.com/content/early/2022/11/24/tc-2022-057639>.

³⁵ *Id.* at 7.

³⁶ *Id.* at 2. Indeed, PMI's own qualitative and quantitative studies, submitted to FDA in support of its modified risk application, showed that "reduced exposure claims are likely to be perceived as reduced risk claims and will, therefore, mislead the public." Lucy Popova et al., *Light and mild redux: heated tobacco products' reduced exposure claims are likely to be understood as reduced risk claims*, 27 (Suppl. 1) TOBACCO CONTROL s87, s91-92 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6202239/>.

³⁷ Berg et al., *supra*, at 2.

³⁸ *Id.* at 7.

Another recent study shows that PMI's misleading messaging is reflected in news coverage of the FDA exposure modification order in low- and middle-income countries. A survey of news articles mentioning the FDA order appearing in the months following its issuance found that 52% of them incorrectly stated that FDA has determined IQOS to be a reduced risk product or that IQOS is a reduced harm product, while 38% of the articles correctly described the FDA order by using only reduced exposure language.³⁹ According to the authors, these results suggest that "reduced exposure is sometimes misreported as reduced risk in the news media," which is "consistent with findings from independent experimental studies and studies of consumer understanding submitted by PMI as part of their MRTP application, which found that consumers who viewed reduced exposure claims reported lower risk perceptions."⁴⁰ For example, a May 2023 Greek news article covering a presentation by the head of PMI Europe incorrectly reported that the FDA "has approved IQOS . . . as a **differentiated risk tobacco product . . .**" in an article discussing "harm reduction" achieved through tobacco products of "differentiated risk."⁴¹

This research raises serious questions as to whether PMI's IQOS products can satisfy the requirements of Section 911(g)(2) that, with regard to authorization of a reduced exposure product, there must be a finding that "consumers will not be misled into believing that the product" is "less harmful" or presents "less of a risk of disease than 1 or more other commercially marketed tobacco products." In light of PMI's statements, and public perceptions, following the 2020 exposure modification order, there should be a heavy presumption that FDA cannot make such a finding for IQOS.

III. FDA'S OWN CONCLUSIONS SUPPORTING A PROHIBITION OF MENTHOL CIGARETTES UNDERCUT ANY JUSTIFICATION FOR CONTINUED OR FUTURE AUTHORIZATION OF MENTHOL-FLAVORED IQOS

The marketing orders granted by FDA for IQOS include "Smooth Menthol" and "Fresh Menthol" Heatsticks (which have been renamed "Green Menthol" and "Blue Menthol" respectively). FDA also has authorized modified exposure claims for these menthol IQOS products. The marketing and modified risk applications for ILUMA also include the brands TEREAL BLUE and TEREAL GREEN, which presumably are menthol-flavored as well. Since FDA issued the marketing orders and modified risk orders for IQOS products, including the menthol-flavored products, the agency has proposed a Rule prohibiting menthol as a characterizing flavor in cigarettes, which has been transmitted as a Final Rule for review by the Office of Information and Regulatory Affairs at the Office of Management and Budget. In the preamble to the Proposed Rule, FDA requested comment on possible exceptions to the menthol Rule for certain products that meet the definition of "cigarette" in the Rule including "noncombusted" products.⁴² In comments on the Proposed Rule, over 100 public health, medical,

³⁹ Meagan O. Robichaud et al., *How Media Stories in Low- and Middle-Income Countries (LMICs) Discussed the US Food and Drug Administration's (FDA's) Modified Risk Tobacco Product (MRTP) Order for IQOS*, 25 NICOTINE & TOBACCO RESEARCH 1659, 1661 (2023), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10445252/>.

⁴⁰ *Id.* at 1663.

⁴¹ <https://www.protagon.gr/epikairota/to-mellon-xwris-tsigaro-pernaei-apo-tin-ellada-44342719064> (May 11, 2023) (emphasis added) (certified English translation attached as Exhibit 9).

⁴² FDA, Proposed Rule, Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,487 (May 4, 2022) ("Proposed Menthol Rule").

education, civil rights and community organizations argued that no such exception for IQOS or other heated products would be appropriate for the protection of the public health.⁴³

In the Preamble to the Proposed Rule on Menthol Cigarettes, FDA concluded that “menthol in cigarettes increases smoking initiation.”⁴⁴ By producing “a minty taste and cooling sensation when inhaled” menthol makes cigarettes more palatable for new users and facilitates “experimentation and regular use, particularly among younger smokers.”⁴⁵ These findings, premised on menthol’s sensory effects, likely would also apply to heated cigarettes that contain menthol, such as menthol-flavored IQOS products, including ILUMA.

FDA also found that the interaction of menthol and nicotine in the brain enhances nicotine addiction, particularly among young people.⁴⁶ According to FDA, “The combined effects of nicotine and menthol in the developing brain make youth who smoke menthol cigarettes particularly vulnerable to the effects of menthol on nicotine dependence.”⁴⁷ These findings rest on menthol’s flavor and sensory effects and the interaction between menthol and nicotine in the brain – features that are present in all IQOS products. Thus, all menthol-flavored IQOS products would be expected to have a similar impact.

Finally, as FDA has established, due to the industry’s decades of targeting Black communities, and other underserved populations, with marketing for menthol cigarettes, their continued presence on the market substantially contributes to disparities in cigarette use and the resulting disparities in health outcomes. In proposing the Rule to prohibit menthol as a characterizing flavor in cigarettes, FDA determined that “[m]embers of underserved communities, such as African American and other racial and ethnic populations, individuals who identify as LGBTQ+, pregnant persons, those with lower household income or educational attainment, and individuals with behavioral health disorders are more likely to report smoking menthol cigarettes than other population groups” and thus “bear a disproportionate burden of tobacco-related morbidity and mortality.”⁴⁸ There is a significant risk that these same population groups will be disproportionately represented among users of IQOS menthol-flavored products, with resulting increased addiction and dual use, without countervailing smoking cessation benefits.

Indeed, IQOS menthol products may significantly undermine achievement of the smoking cessation goals set by the *HHS Framework to Support and Accelerate Smoking Cessation 2024*, particularly as to Black communities and other underserved populations that are the focus of the *Framework*.⁴⁹ As FDA has found, “The totality of scientific evidence on menthol

⁴³ Comments filed in Docket No. FDA-2021-N-1349 (August 2, 2022), at 29-30, https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/Support_Prohibiting_Menthol_Cigarettes_8_2_2022.pdf.

⁴⁴ Proposed Menthol Rule, 87 Fed. Reg. at 26,463.

⁴⁵ *Id.*

⁴⁶ *Id.* at 26,468.

⁴⁷ *Id.* at 26,465.

⁴⁸ *Id.* at 26,458.

⁴⁹ <https://www.hhs.gov/sites/default/files/hhs-framework-support-accelerate-smoking-cessation-2024.pdf>.

and cessation supports the conclusion that menthol cigarettes contribute to reduced cessation success, particularly among Black smokers.”⁵⁰

Thus, FDA’s conclusions supporting a prohibition of menthol cigarettes contradict any justification for continued or future authorization of menthol-flavored IQOS.

Conclusion

The undersigned urge FDA, in considering PMI’s marketing and modified risk applications for IQOS, to take into account these recent developments, as they directly bear on whether PMI should be permitted to market IQOS in the U.S. and whether it should be permitted to make modified risk claims in connection with IQOS.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

⁵⁰ Proposed Menthol Rule, 87 Fed. Reg. at 26,468.

EXHIBIT 1

An Examination of Philip Morris International's Estimate of IQOS Consumers Who Have “Completely Transitioned” From Cigarettes: Findings From the 2018/19 and 2020 ITC Japan Surveys

Shannon Gravely¹, Gang Meng¹, Steve Shaowei Xu¹, Christian Boudreau¹,
Mary Thompson¹, Takahiro Tabuchi², Kota Katanoda³, Itsuro Yoshimi⁴,
K. Michael Cummings⁵, Andrew Hyland⁶, and Geoffrey T. Fong^{1,7}

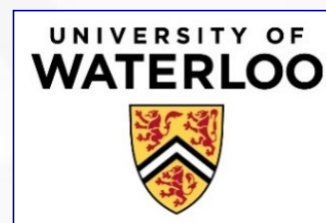
¹ University of Waterloo, Canada; ² Cancer Control Center, Osaka International Cancer Institute, Japan; ³ Japan National Cancer Center, Japan;

⁴ National Cancer Center Japan; ⁵ Medical University of South Carolina, USA; ⁶ Roswell Park Comprehensive Cancer Center, USA;

⁷ Ontario Institute for Cancer Research



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San Antonio, Texas, USA



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The authors have no relationships with industry to disclose

Disclosures of Interests:

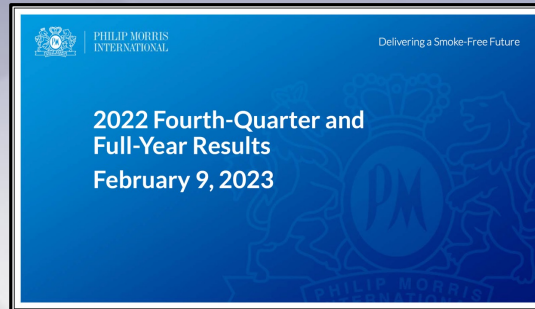
- Kota Katanoda received a JMWH Bayer Grant from Sep. 1, 2017 to Aug. 31, 2019 via the Japan Society for Menopause and Women's Health.
- Geoffrey T. Fong has served as an expert witness or consultant for governments defending their country's policies or regulations in litigation.
- Geoffrey T. Fong and Shannon Gravely served as paid expert consultants to the Ministry of Health of Singapore in reviewing the evidence on plain/standardized packaging.
- K. Michael Cummings has served as a paid expert witness in litigation against cigarette manufacturers in the United States.
- All other authors including the presenter have no conflict of interests to declare.

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The ITC Japan Project was supported by the Japan National Cancer Center and Research Development Fund (28-A-24) and the Canadian Institutes of Health Research Foundation Grant (FDN-148477). Additional support to GTF is provided by a Senior Investigator Grant from the Ontario Institute for Cancer Research (IA-004). The funding agencies did not have any role in study design, collection, analysis, and interpretation of the data.

Background

- Philip Morris International (PMI) quarterly reports include information about the performance and growth of IQOS
- As of 2022, IQOS was being sold in nearly 70 countries
- 2021: 28% of PMIs net revenues
- Volume, growth, success in converting people who smoke to IQOS

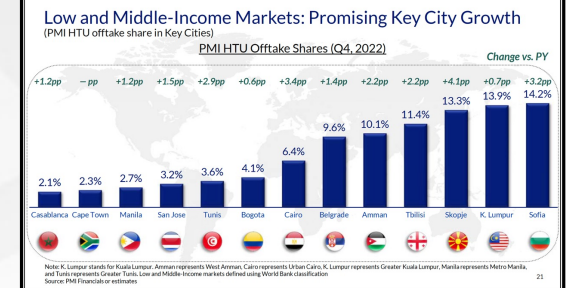
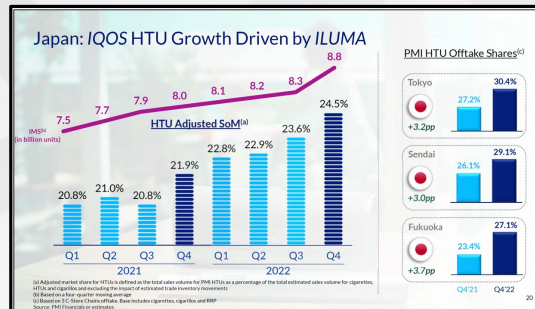


2022: Remarkable Year for Our Smoke-Free Transformation

- Very strong delivery despite exceptional challenges
- Second consecutive year of total volume growth
- ~1/3 smoke-free net revenues for total PMI
- Outstanding IQOS performance supported by ILUMA and 2-tier HTU portfolio
- Robust growth in combustible net revenues and share of segment
- Major steps forward in our smoke-free transformation – IQOS in the U.S. and Swedish Match acquisition^(a)



(a) As of April 30, 2024 PMI will have the full rights to commercialize IQOS in the U.S.
Source: PMI Executive or estimates



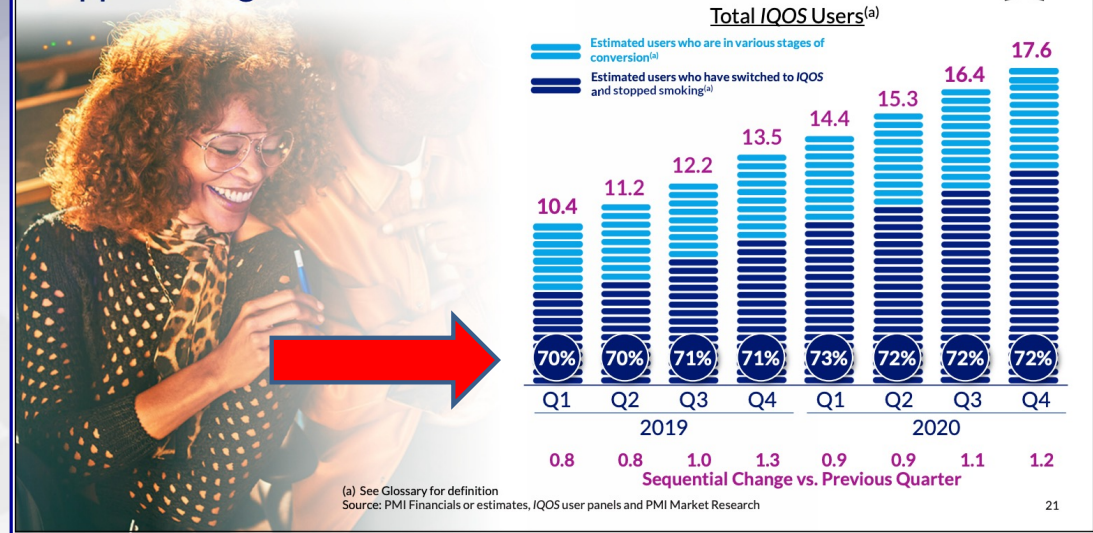
Have IQOS consumers stopped smoking?

PMI Definition:

“Completely Transitioned”

At least 95% of total tobacco consumption is from HTPs

Approaching 18 Million Users in 2020

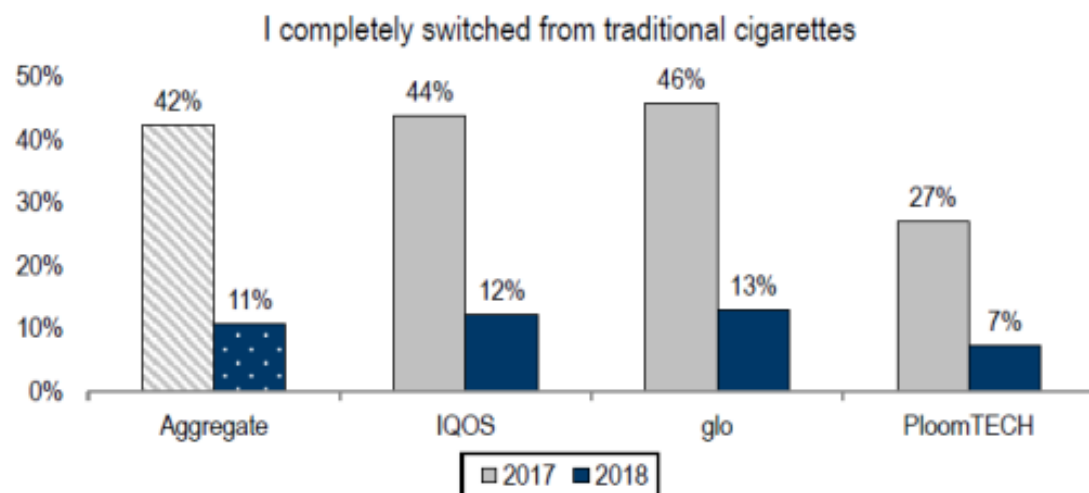


PMI reports that in their IQOS Customer Survey, the percentage of IQOS consumers who had completely transitioned from cigarettes was:

- 70% in Q1 2019
- 72% in Q2 2020

What do non-industry studies say?

Figure 1: High dual use in 2018 CS Japan Survey



Source: Credit Suisse 2017 & 2018 Tobacco Consumer Survey

Industry-independent studies in Japan using nationally representative data have shown that about **2/3 of HTP consumers are continuing to smoke cigarettes.**

That is, **only about 1/3 of HTP consumers have “completely transitioned.”**

(Tabuchi et al. 2018; Santos et al. 2019)

Important for industry-independent studies to test PMI's reports that 70-72% of IQOS consumers have "completely transitioned" from cigarettes to IQOS (and other HTPs)

Study Objectives

- Cross-sectional study using national data from the ITC Japan Surveys at:
 - Wave 2 (Dec 2018-Feb 2019) and
 - Wave 3 (May-Jun 2020) to calculate:
 - The proportion of HTP consumers who have “completely transitioned” ($\geq 95\%$ HTPs) for:
 - (1) IQOS
 - (2) All HTPs (leading brands: IQOS, Ploom TECH & glo)
 - Compare ITC proportions to PMI's



ITC Japan Survey & PMI Japan IQOS Customer Survey



	ITC	PMI
Survey type	Online	Online
Survey design	Cohort sample with replenishment	Cross-sectional
Respondent Source	Rakuten Insight (survey firm)	IQOS users registered on the PMI IQOS User Database
Data source	Wave 2 (Dec 2018-Feb 2019) Wave 3 (May-Jun 2020)	Year 3 (2019). Source: Q1 2019 report Year 4 (2020-2021). Source: Q2 2020 report
Eligibility criteria	Use HTPs $\geq$ weekly	Past 30-day IQOS consumers
	Aged 20+ years	Aged 20+ years
	Used $\geq$ 100 HTP sticks/lifetime	Used $\geq$ 100 HTP sticks/lifetime
HTPs	HTPs: IQOS, glo, Ploom TECH	IQOS and other HTPs (brands not stated)
Sample size	W2: N=520 IQOS, 543 other HTPs W3: N=854 IQOS, 656 other HTPs	Year 3: N=2013 IQOS users Year 4: N=2000 IQOS users

*ITC: people who currently and formerly smoked (<weekly cigarette use and former smoking, consumption of cigs = 0)

Analyses of the ITC Japan Survey data

- Cross-sectional weights were original ITC weights (using JASTIS* surveys as the benchmark) recalibrated to PMI's sex * age distribution.
- We did this to adjust the ITC data so that it was more comparable to the PMI data.
- Each Ploom TECH capsule x 4 to get number of equivalent HTP sticks

Cigarettes (CPD)+ HTPs (HPD) =
total consumption (TPD)

HPD/TPD = proportion of total
consumption from HTPs

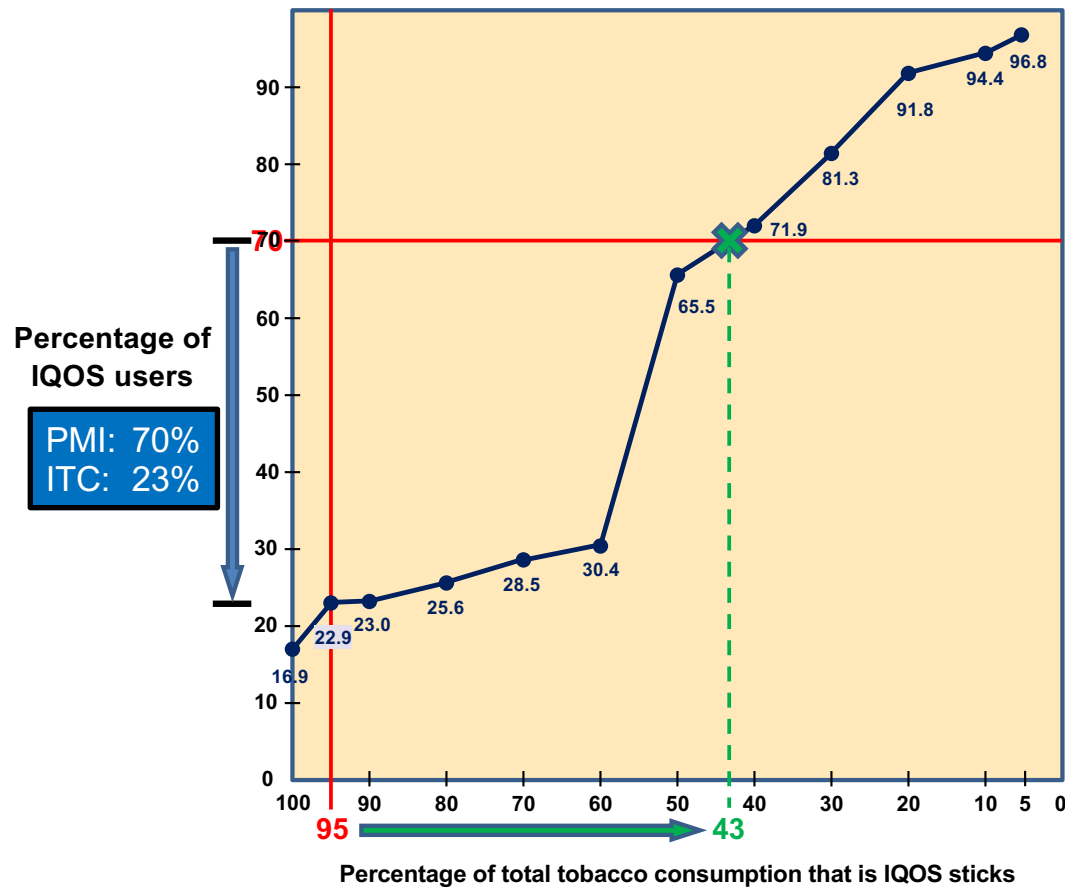


Construct the cumulative
distribution of the HPD/TPD ratio
from **highest** (100% and 95%:
“completely transitioned”)
to **lowest** (5% and 0%:
exclusive smoking)

*Japan “Society and New Tobacco” Internet Survey (JASTIS); HPD: HeatSticks per day; CPD: cigarettes per day

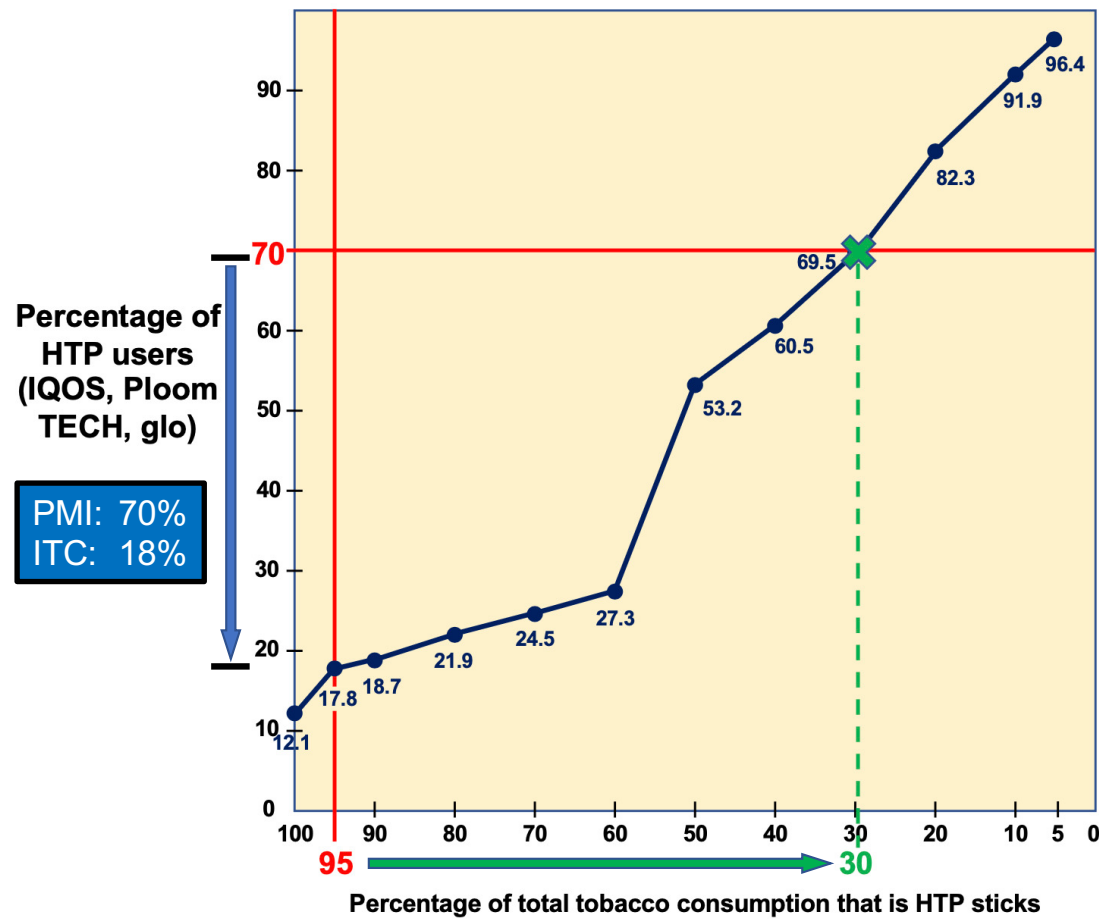


ITC Japan W2 (2018/19) vs. PMI (Q1 2019): ITC IQOS Consumers (N=520)



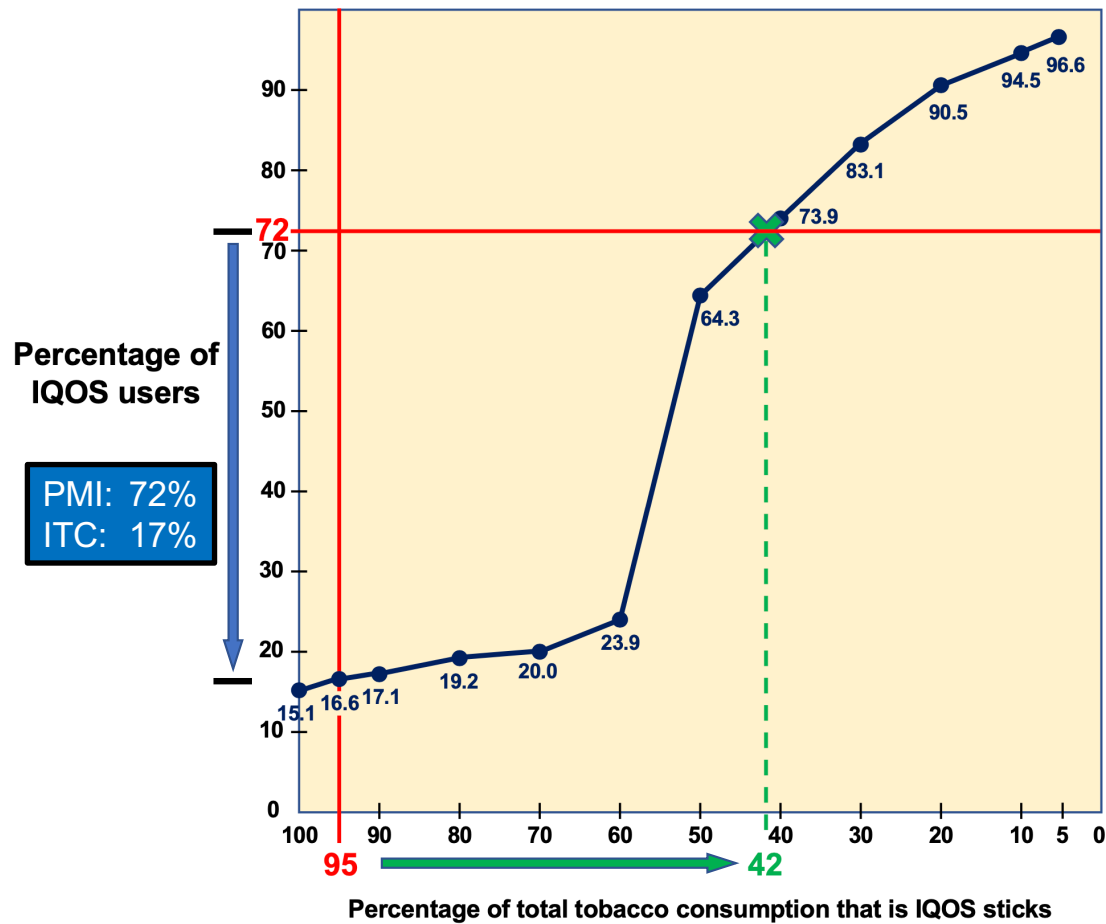
* Weighted to PMI age x sex distribution

ITC Japan W2 (2018/19) vs. PMI (Q1 2019): ITC **All HTP Consumers** (N=1063)



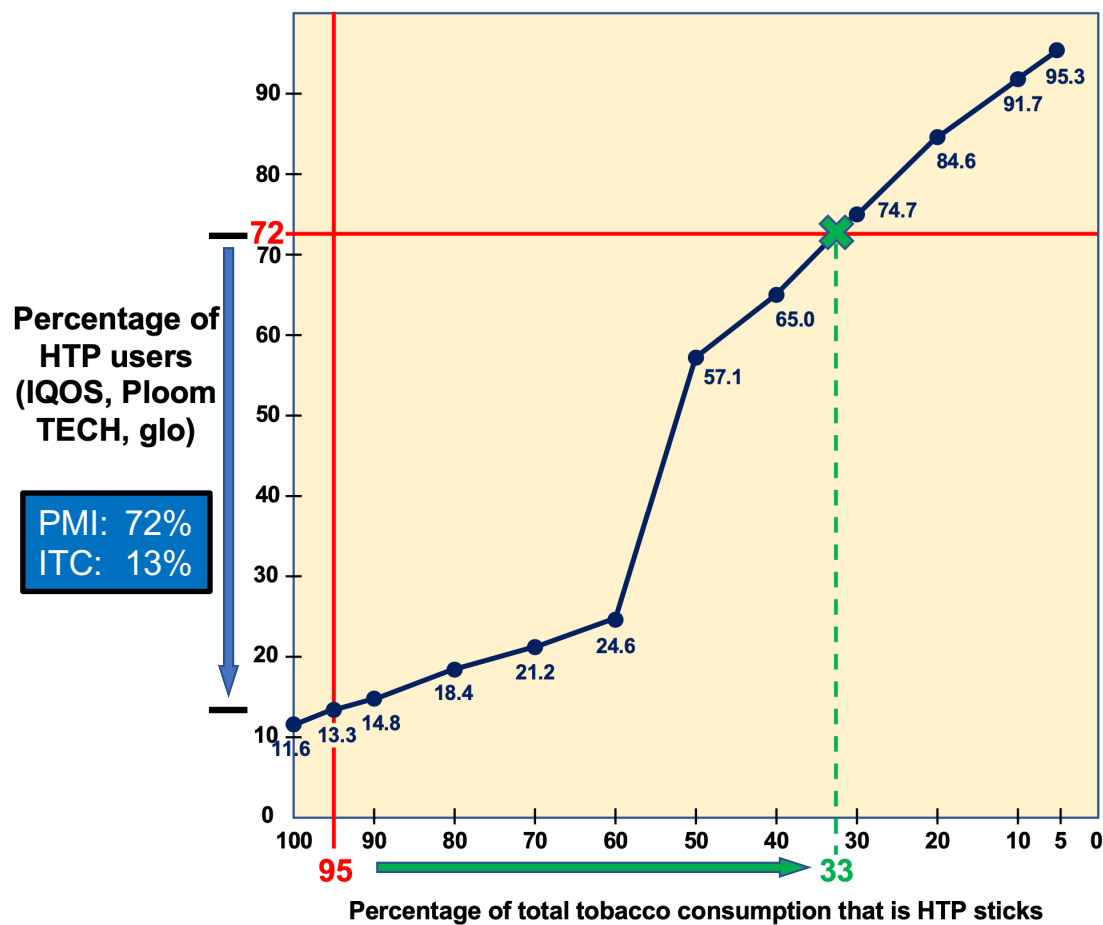
* Weighted to PMI age x sex distribution

ITC Japan W3 (2020) vs. PMI (Q2 2020): IQOS Consumers (N=854)



* Weighted to PMI age x sex distribution

ITC Japan W3 (2020) vs. PMI (Q2 2020): **All HTP Consumers** (N=1510)



* Weighted to PMI age x sex distribution

Summary

Data Source	% Completely Transitioned	
	2019	2020
PMI Shareholder Report from IQOS User Survey: % of IQOS Users who were completely transitioned	70%	73%
ITC: IQOS Users	23%	17%
ITC: All HTP Users	18%	13%

Summary and Conclusion

- Large discrepancy between the ITC data and the PMI data on the percentage of IQOS consumers who have “completely transitioned” from cigarettes: ITC percentages were much lower.
- Dual use is by far the dominant use pattern of those who use IQOS and other HTPs.
- IQOS customers in the survey may be more likely to be those who have completely transitioned: satisfaction with product is higher, which is strongly linked to having quit cigarettes (Xu et al.–reasons for using HTPs: 55% use HTPs because HTPs might help them quit).
- **These findings highlight the importance of non-industry research on use patterns of HTPs, particularly how HTPs interact with cigarettes.**

Major Support for the ITC Project



US National Cancer Institute
P01 CA200512



Canadian Institutes of Health Research
FDN-148477



Ontario Institute for Cancer Research
Senior Investigator Award (2007-2027)

ITC Project Research Organizations



ITC Project Research Support



EXHIBIT 2

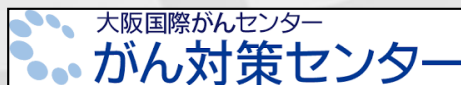


International Tobacco Control
Policy Evaluation Project

Transitions of Tobacco Product Use Among Adults Who Smoke Cigarettes and Adults Who Use Heated Tobacco Products (HTPs) in Japan: Initial Findings from Three Waves of the ITC Japan Cohort Survey (2018-20)

Geoffrey T. Fong^{1,2*}, Gang Meng¹, Shannon Gravely¹, Mary E. Thompson¹,
Steve Shaowei Xu¹, Anne C. K. Quah¹, Janine Ouimet¹, Itsuro Yoshimi³,
Kota Katanoda³, Takahiro Tabuchi⁴, K. Michael Cummings⁵, Andrew Hyland⁶

¹University of Waterloo, Canada; ²Ontario Institute for Cancer Research, Canada; ³Japan National Cancer Center, Japan; ⁴Osaka International Cancer Institute, Japan; ⁵Medical University of South Carolina, USA; ⁶Roswell Park Comprehensive Cancer Center, USA;



Presented at Society for Research on Nicotine and Tobacco
29th Annual Meeting, March 3, 2023

St. Antonio, Texas

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Disclosures and Funding

The authors have no relationships with industry to disclose

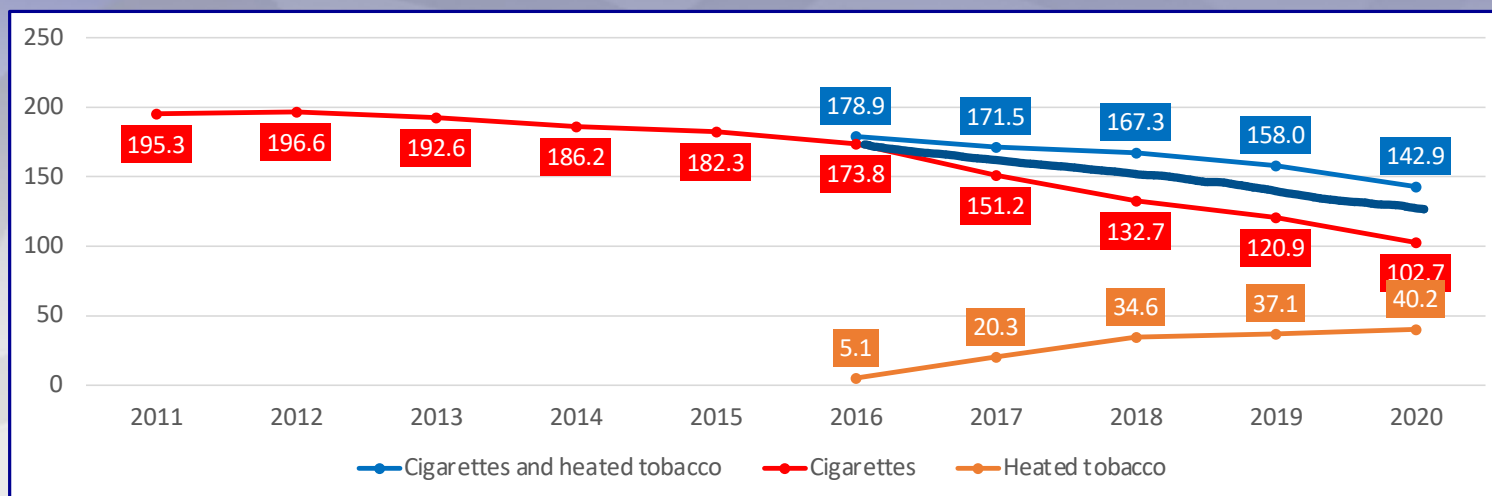
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Introduction: The emergence of HTPs in Japan and the decline of cigarettes



- Japan's tobacco landscape has changed significantly with the introduction of HTPs
- Before HTPs came on the market, cigarette sales were slowly decreasing.
- After HTPs were introduced nationally in September 2015:
 - Cigarette sales have decreased more rapidly.
 - HTP consumption continued to increase.
 - Cigarettes have been partially replaced by HTPs.

Article

What Is Accounting for the Rapid Decline in Cigarette Sales in Japan?

K. Michael Cummings^{1,*}, Georges J. Nahhas¹ and David T. Sweanor²

Digging deeper: what is the interaction between cigarettes and HTPs at the individual level?

- We know that there are enormous changes taking place in Japan's tobacco market.
- The sales data are **consistent** with the idea that cigarettes are being substituted for HTPs, but these are **aggregate data**.
- It is important to understand the interplay between cigarettes and HTPs at the **individual level**:
 - To what extent are people who smoke taking up HTPs, and when they do, does this lead to quitting cigarettes, quitting HTPs and going back to cigarettes only, or quitting both cigarettes and HTPs?
 - The proportions of these transitions are critically important for making assessments of the population-level effects.
 - Are patterns of use stabilizing over time? For example: What are the expected long-term tobacco use patterns for HTP users: long-term dual use or long-term exclusive HTP use?
 - By examining transitions at the individual level, it is also possible to identify the factors associated with each kind of transition.
 - These individual-level analyses are only possible with a longitudinal cohort design.

The ITC Japan Cohort Surveys

- 4 waves conducted: JP1 in 2018, JP2 in 2018-19, JP3 in 2020, JP4 in 2021
- Recruitment from high quality national web panel (Rakuten Insight)
- Survey design: Longitudinal with replenishment, with quotas each wave on:
 - Cig-only: cigarettes only at least monthly (cig-only), those who use HTPs only at least weekly, those who use both products (dual), and non-users.
- Survey weights calibrated to results from the JASTIS survey make the data representative of the adult population at each wave.
- Retention between waves: 66%

Table 3: JP3 target and valid sample with retention and replenishment numbers by subsample

Subsample group	JP2 final N	JP3 target N	JP3 recontacted N	JP3 replenished N	JP3 final N
Current exclusive smokers (including recontact cigarette quitters)	1,911	2,000	1,205	643	1,848
Current exclusive HTP-users (including recontact HTP-only quitters)	931	1,000	468	501	969
Current cigarette-HTP dual users (including recontact cigarette-HTP quitters)	895	1,000	660	249	909
Never or non-users	491	500	462	294	756
Total	4,228	4,500	2,795	1,687	4,482

Basic table of transitions in product use between waves

Wave 1		Wave 2				Total
		Cig only	Dual	HTP only	Neither Product	
Cig only	N	1478	483	41	100	2102
	%	69.6	22.5	1.8	6.1	
Dual	N	41	198	19	10	268
	%	18.7	71.7	6.4	3.3	
HTP only	N	2	14	42	4	62
	%	5.0	26.1	62.8	6.1	
Recent Quitter	N	11	4	1	25	41
	%	31.8	10.4	0.7	57.2	
Total		1532	699	103	139	2473

Wave 2		Wave 3				Total
		Cig only	Dual	HTP only	Neither Product	
Cig only	N	974	134	38	80	1226
	%	77.7	12.4	3.3	6.7	
Dual	N	209	352	68	17	646
	%	30.0	56.1	11.7	2.3	
HTP only	N	10	183	329	42	565
	%	5.3	32.5	45.4	16.7	
Recent Quitter	N	16	8	4	17	61
	%	44.0	6.8	3.4	45.9	
Total		1209	677	439	173	2498

Percentages are weighted and adjusted by sex, age group, and time in sample • Cig only: those who smoke at least monthly • HTP only: those who use HTPs at least weekly
- Recent Quitters at baseline are short term quitters (<2y) and people who smoke very occasionally (< monthly).

It's not so simple—challenges in drawing conclusions from the transition tables

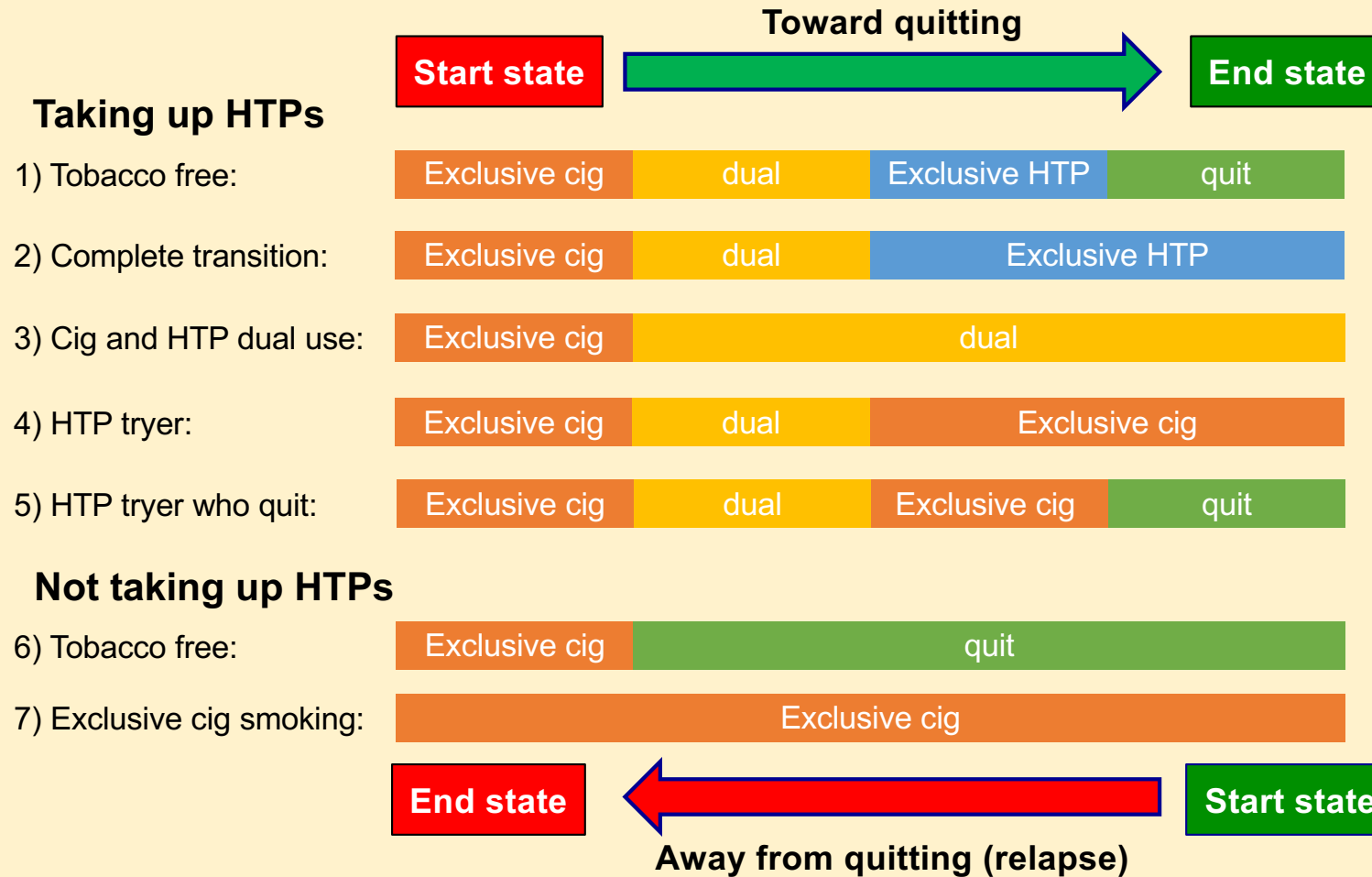
- Transition tables provide initial information about how each of the four user groups changed or didn't change between waves (W1 to W2 = 10-11 months).
- The simple transition tables capture population movement but may be misleading with respect to individual histories: they over-represent the experience of individuals who have occupied initial Dual or HTP-only states for a longer period of time (**length biased sampling**).
- Another challenge: who were dual using who quit smoking prior to the recruitment into the survey are not included, but those who are dual using who haven't yet quit smoking (or have tried to quit but failed) are included. (**"treatment failure" issue**)
- Any survey (longitudinal or not) is taking a **snapshot of a movie**: the flow of individuals through a journey of product use, with some staying in a particular state for a long time, others for a short time.
- What can we do to do better measure and understand this process?

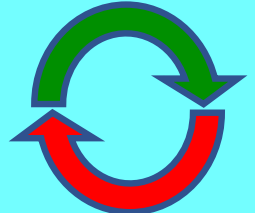
Possibilities for improving our snapshots of a movie

- Don't start with those who dual use. Instead start with those who only smoke cigarettes and then follow them through their transition states. This deals with the “failed quitters” challenge.
- Distinguish between more transient, short-term states of use and more stable, longer-term states of use. That extends the timeframe of the snapshots that we are taking in our surveys. (iPhone “live” photo option)
- Examine transitions over more than 2 waves: enabling some inferences about whether the transitions between products and use states is changing as HTPs have become more established in the Japan tobacco marketplace.



Theoretical transition stages for exclusive cigarette smokers who initiate/do not initiate HTPs




 But for many/most, these transitions are not linear.

Population cross-section proportions of different states of product use

	Wave 1	Wave 2	Wave 3
Cig only & never regular HTP use	84.8%	53.5%	52.6%
Cig only & ever regular HTP use	4.9%	9.8%	20.6%
Short term dual (< 6 months)	2.9%	14.2%	4.6%
Long term dual (6 months or more)	2.5%	17.4%	19.9%
HTP only	4.8%	5.0%	2.3%
Total	100.0%	100.0%	100.0%

Evidence of the possible emergence of a stable class of people who are engaging in long-term dual use

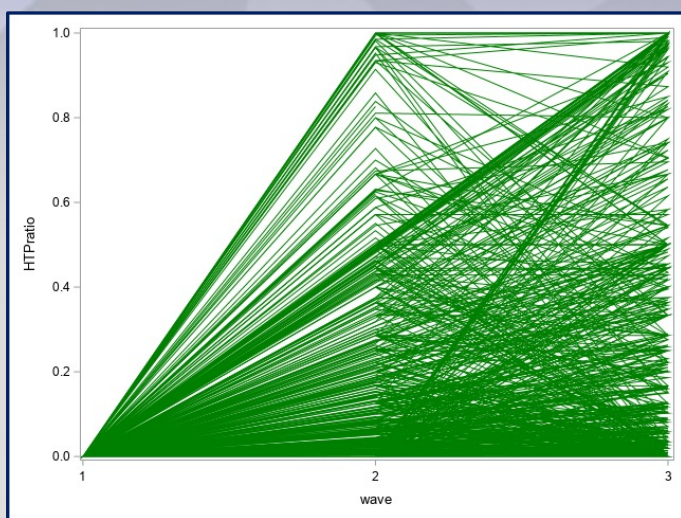
Expanded Transition Matrix for Cig-Only at Baseline

Baseline survey		Follow-up survey									
		Cig only		Dual		HTP only		Quitters			
		never used HTP regularly	ever used HTP regularly	Short-term	Long-term	Short-term	Long-term	ever used HTP regularly		never used HTP regularly	
								Short-term	Long-term	Short-term	Long-term
Cig only	never used HTP regularly	X	X	X	X	X	X	X	X	X	X
	ever used HTP regularly		X	X	X	X	X	X	X		
Dual	Short-term		X	X	X	X	X	X	X		
	Long-term		X	X	X	X	X	X	X		

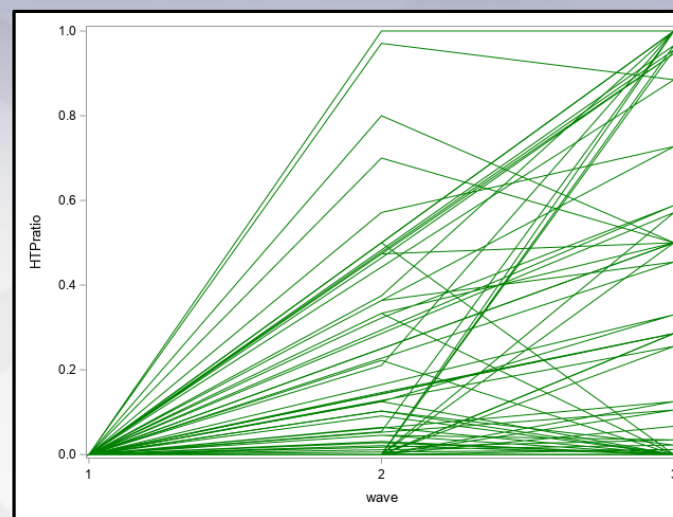
- The table decomposes each group into **stable/long-term**: those who report having been in the state that they are in at the time of the survey for at least 6 months vs **transient/short-term**: those who have not been in the state for less than 6 months. We use this expanded table in the analyses that follow
- This expanded transition matrix addresses length-bias at baseline: short-term dual use is a transient stage; long-term dual use is a relatively stable stage.
- Enables us to estimate long-term tobacco use patterns at follow up.
- Avoids “treatment failure” problem. Including just exclusive smokers who never used HTP regularly at baseline would provide a clean start point where samples with “no treatment” were included. Eliminating fluctuations at follow-up would compare those who are “affected” by HTP use with those who are “not affected” by HTP use.

Individual-Level Transitions at a Glance

Wave 1 cig only smokers who had
NEVER used HTP



Wave 1 cig only smokers who
HAD ever used HTP



- A lot of dual use (the points between the top and bottom)
- Transitions from dual use to exclusive smoking are more frequent (bottom) than to HTP only (top)
- A majority of respondents who picked up HTPs remained using a relatively lower amount of HTPs compared to cigarettes (greater density in the lower regions of the figure than the upper regions)
- Not many straight lines from Waves 2 to 3: not much stability over time. Lot of experimentation with HTPs.

Expanding the transition matrix: W1 to W2 and to W3

wave 1 (2018)	wave 2 (2019)																		
	cig only & never regular HTP use		cig only & ever regular HTP use		short-term dual		long-term dual		short-term HTP only		long-term HTP only		quitter ever used HTP		short-term quitter never used HTP		long-term quitter never used HTP		Total
	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=
cig only & never regular HTP use	907	66.9	67	6.1	275	18.3	73	4.5	14	0.9	5	0.5	3	0.5	17	1.8	8	0.5	1369
cig only & ever regular HTP use			49	62.8	14	17.6	14	16.4	2	1.5	0	.	1	1.6					80
short-term dual (<6m)			15	19.2	11	16.3	64	62.2	0	.	2	2.3	0	.					92
long-term dual (6m+)			8	8.3	4	8.8	63	76.9	0	.	4	3.2	2	2.9					81
Total	907		139		304		214		16		11		6		17		8		1622

wave 1 (2018)	wave 3 (2020)																		
	cig only & never regular HTP use		cig only & ever regular HTP use		short-term dual		long-term dual		short-term HTP only		long-term HTP only		quitter ever used HTP		short-term quitter never used HTP		long-term quitter never used HTP		Total
	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=
cig only & never regular HTP use	733	53.5	240	17.5	72	5.8	214	14.8	8	0.4	22	1.4	25	1.8	19	1.3	39	3.6	1372
cig only & ever regular HTP use			44	51.8	5	8.4	19	23.2	1	2.7	6	7.2	5	6.8					80
short-term dual (<6m)			28	31.0	6	5.8	47	52.5	2	1.7	7	8.6	1	0.5					91
long-term dual (6m+)			11	14.3	2	3.5	54	70.5	0	.	10	7.2	4	4.5					81
Total	733		323		85		334		11		45		35		19		39		1624

- Data are weighted but unadjusted. The difference in n for baseline cig only % never regular HTP user between the two tables is dual to missing HTP use durations.

- About half of the never HTP users in 2018 tried HTPs between 2018 and 2020: HTPs increased dramatically in popularity
- Transitioning from exclusive smoking to long-term dual was MUCH more likely (14.8%) than transitioning to HTP only (1.4%)
- Those who were long-term duals in 2018 stayed in that state (70.5%); more than half (52.5%) of short-term duals became long-term duals, showing that starting off in dual use leads to dual use as a stable state.

1. Is Long-Term HTP use associated with a greater likelihood of quitting cigarettes?

wave 1 (2018)	wave 3 (2020)												Difference (P-value)
	cig only & never regular HTP use		long-term quitter never used HTP		Long-term quit among never HTP users	long-term dual		long-term HTP only		Long-term quitter who ever long- term used HTP		Long-term quit among long-term HTP users	
	N=	%	N=	%	%	N=	%	N=	%	N=	%	%	
cig only & never regular HTP use	733	53.5	39	3.6	$3.6/(3.6+53.5)$ =6.3	214	14.8	22	1.4	1	0.1	$1.4+0.1/(1.4+0.1+14.8)$ =9.2	Diff=2.9% (p=0.34)

NO, it is not—a non-significant (p=.34) trend

Long-term HTP users (N=237) = 9.2%

Never HTP users (N=772) = 6.3%

2. Is Long-Term HTP use associated with a greater likelihood of quitting cigarettes among daily smokers vs. non-dailys?

wave 1 (2018)		wave 3 (2020)												Difference (P-value)
		cig only & never regular HTP use		long-term quitter never used HTP		long-term quit among never HTP users	long-term dual		long-term HTP only		Long-term quitter who ever long- term used HTP		long-term quit among long-term HTP users	
		N=	%	N=	%	%	N=	%	N=	%	N=	%	%	
cig only & never regular HTP use	Daily smoker	704	53.4	35	3.5	$3.5/(3.5+53.4) = 6.2$	204	14.7	21	1.4	1	0.1	$(1.4+0.1)/(1.4+0.1+14.7) = 9.3$	Diff=3.1% (p=0.31)
	Non-daily smoker	29	53.8	4	5.9	$5.9/(5.9+53.8) = 9.9$	10	15.2	1	1.1	0	0	$1.1/(1.1+15.2) = 6.6$	Diff=-3.3% (p=0.70)

NO, it is not—a (p=.31) trend for daily and no difference for non-daily (p=.70)

Daily

Long-term HTP (N=226) = 9.3%

Never HTP (N=739) = 6.2%

Non-Daily

Long-term HTP (N=11) = 6.6%

Never HTP (N=33) = 9.9%

3. Is Long-Term HTP use associated with a greater likelihood of daily smokers transitioning to non-daily smoking?

Non-daily smoking is a precursor for future quitting

wave 1 (2018)	wave 3 (2020)										
	daily cig only & never regular HTP		non-daily cig only & never regular HTP use		cig reduction among never HTP users	daily cig long-term dual		non-daily cig long-term dual		cig reduction among long-term HTP users	Difference (P-value)
	N=	%	N=	%	%	N=	%	N=	%	%	
Daily cig only & never regular HTP use	684	52.3	18	1.0	1.0/(1.0+52.3) = 1.9	186	13.5	11	0.8	0.8/(0.8+13.5) = 5.4	Diff=3.5% (p=0.08)

Maybe: A trend (p=.08) toward transitioning to non-daily smoking

Long-term HTP users (N=197) = 5.4%

Never HTP users (N=702) = 1.9%

4. Association between ever-using HTPs and: (a) not smoking cigarettes, (b) using neither cigarettes nor HTPs

wave 1 (2018)																			
	cig only & never regular HTP use		cig only & ever regular HTP use		short-term dual		long-term dual		short-term HTP only		long-term HTP only		quitter ever used HTP		short-term quitter never used HTP		long-term quitter never used HTP		Total
	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=	%	N=
cig only & never regular HTP use	733	53.5	240	17.5	72	5.8	214	14.8	8	0.4	22	1.4	25	1.8	19	1.3	39	3.6	1372

Cigarette free

	Denominator (%)	Numerator (%)	Not using any nicotine product at Wave 3(%)	Difference (P-value)
Ever-used HTPs	All groups that ever-used HTPs: $17.5 + 5.8 + 14.8 + 0.4 + 1.4 + 1.8 = 41.7$	cig quitter ever used HTPs: $1.8 + 1.4 + 0.4 = 3.6$	$3.6/41.7$ $= 8.6\%$	Diff = 0.2% (p=0.92)
Never used HTPs	cig only & never regular HTP use + quitter never used HTPs: $53.5 + 1.3 + 3.6 = 58.4$	cig quitter never used HTPs: $1.3 + 3.6 = 4.9$	$4.9/58.4$ $= 8.4\%$	

Tobacco free: Neither cigarettes nor HTPs

	Denominator (%)	Numerator (%)	Not using any nicotine product at Wave 3(%)	Difference (P-value)
Ever-used HTPs	All groups that ever-used HTPs: $17.5 + 5.8 + 14.8 + 0.4 + 1.4 + 1.8 = 41.7$	quitter ever used HTP: 1.8	$1.8/41.7$ $= 4.3\%$	Diff = -4.1% (p=0.02)
Never used HTPs	cig only & never regular HTP use + quitter never used HTPs: $53.5 + 1.3 + 3.6 = 58.4$	quitter never used HTPs: $1.3 + 3.6 = 4.9$	$4.9/58.4$ $= 8.4\%$	

- **Cigarette Free:** no difference between ever-used HTPs (8.4%) and never-used HTPs (8.6%)
- **Tobacco Free:** those who ever-used HTPs from W1 to W3 were significantly less likely (4.3%) than those who never-used HTPs (8.4%)

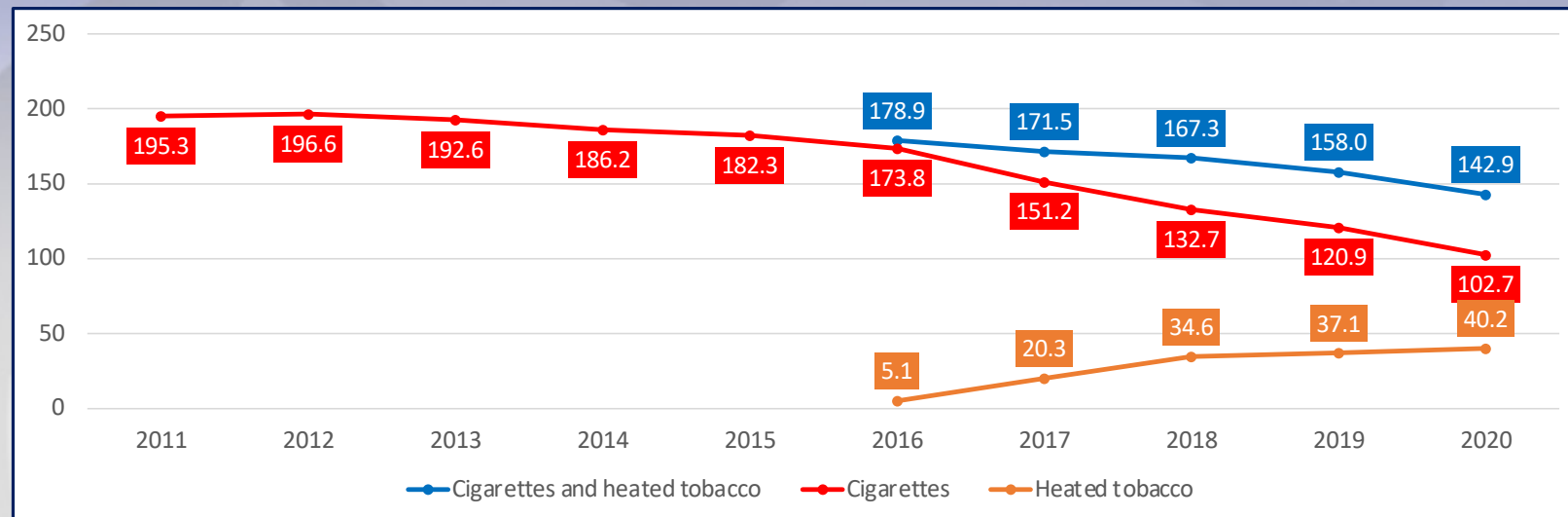
The journey of those who exclusively smoke at W1 (2018) over two years (W2: 2018-19 and W3: 2020)



- The Wave 1 to Wave 3 period (2018-2020) was a period of change for the market in Japan: this was not a period when wave-to-wave transitions are “stationary”.
- By Wave 3 (2020), there was greater stationarity: toward long-term dual use.
- While only 10.8% of those who smoked at Wave 1 had used HTP regularly by that time, by Wave 3, this increased to close to half.
- **Quitting cigarettes among daily smoking** at W1: no diff—long-term HTPs (9.3%) vs. nevers (6.2%)
- **Quitting cigarettes among <daily smoking** at W1: no diff—long-term HTPs (6.6%) vs. nevers (9.9%)
- **Transition from daily smoking to non-daily**: positive trend—long-term HTPs (5.4%) vs. nevers (1.9%)
- **Transition to quit cigarettes**: no diff between ever-tried HTPs (8.6%) vs. never-tried (8.4%)
- **Transition to no tobacco use**: those ever-tried HTPs were less likely (4.3%) vs. nevers (8.4%)

Neither ever-trying HTPs nor using HTPs for a longer period ($\geq 6M$) was associated with quitting cigarettes, and both were negatively associated with transitioning to using neither product.

How can we best interpret the trends in sales of cigarettes and HTPs in Japan?



The dramatic decrease in cigarette sales and the increase in HTP sales in Japan is likely due (nearly) entirely to partial substitution among smokers who are now duals, and likely to become long-term duals rather than due to smokers quitting or transitioning to using neither product.

Next steps in our explorations

- Controlling for covariates and applying regression adjustments to the results of this analysis.
- Questionnaire additions: questions about details of the process of initiating HTPs, length and amount of use, timing of HTP cessation vs cigarette cessation.
- More advanced statistical methods: event history models applied to transitions through relatively stable states: cigarette smoking, long-term dual use, long-term exclusive HTP use, tobacco-free

Major Support for the ITC Project



US National Cancer Institute
P01 CA200512



Canadian Institutes of Health Research
FDN-148477



Ontario Institute for Cancer Research
Senior Investigator Award (2007-2027)

ITC Project Research Organizations



ITC Project Research Support



EXHIBIT 3

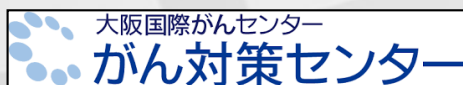


International Tobacco Control
Policy Evaluation Project

Changes in Cigarette and Total Tobacco Consumption Among People Who Smoke Who Did and Did Not Initiate Heated Tobacco Products: Findings from the 2018-2021 ITC Japan Surveys

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Andrew Hyland⁵, Geoffrey T. Fong^{1, 6}**

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29th Annual Meeting, March 3, 2023
San Antonio, Texas
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Disclosures and Funding



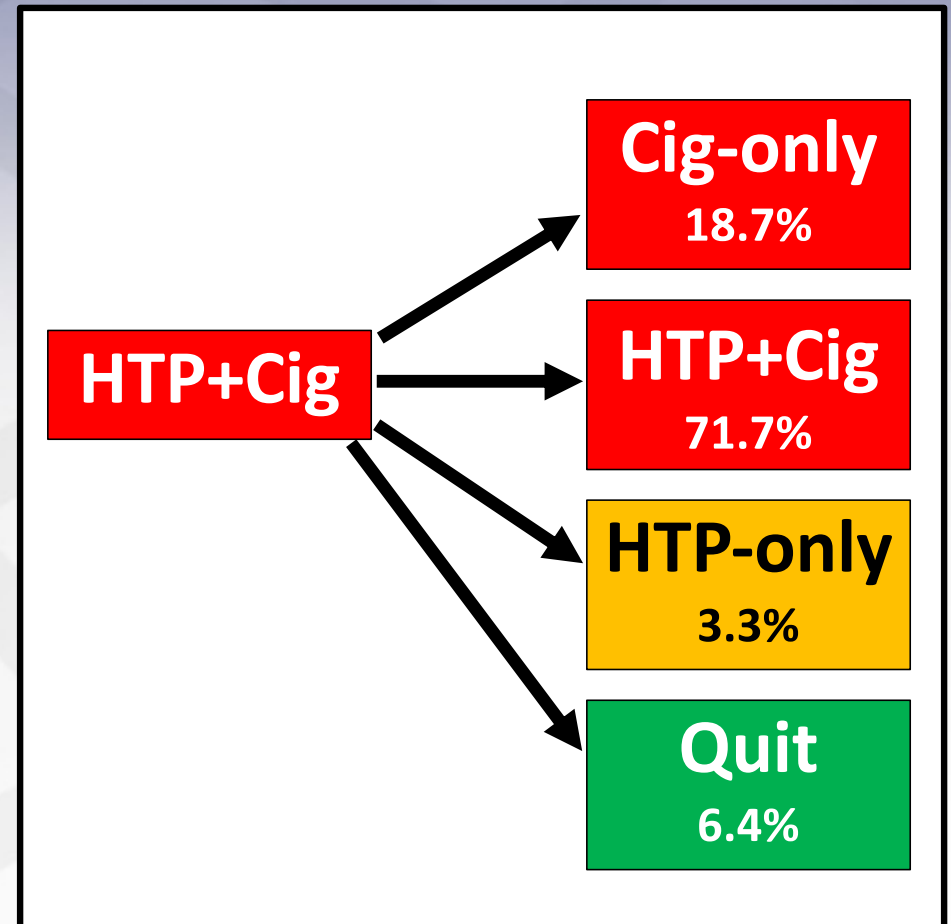
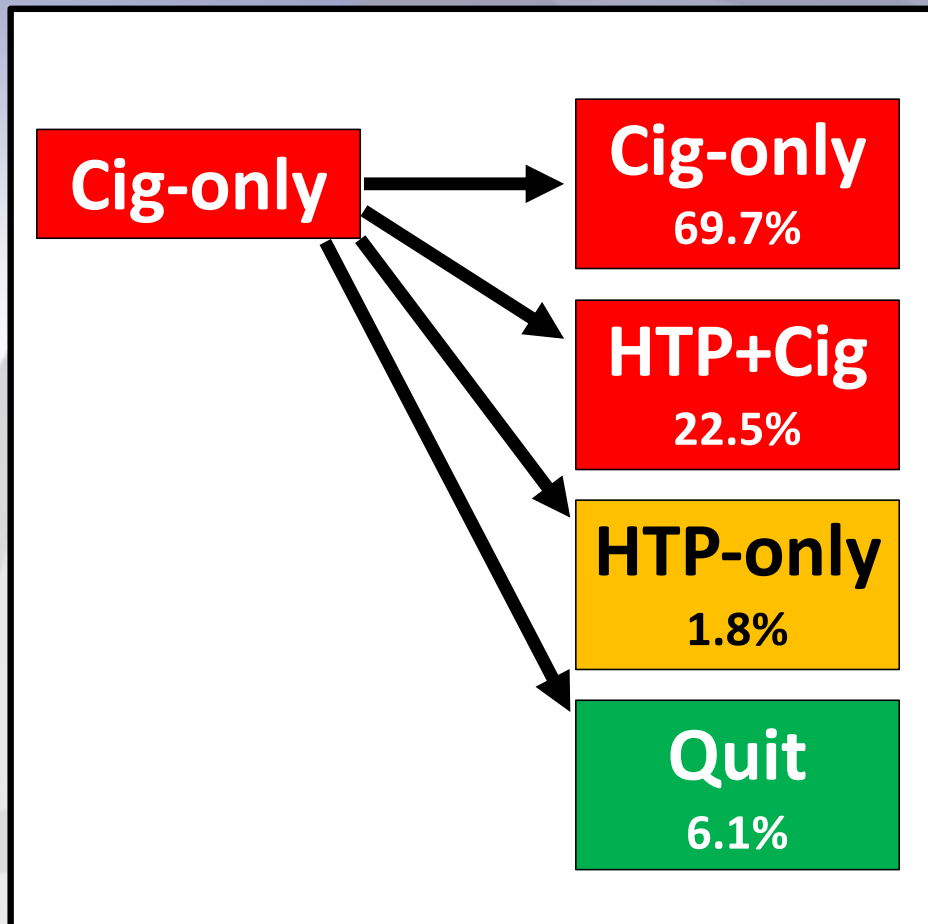
Disclosures of Interest:

- Kota Katanoda received a JMWH Bayer Grant from Sep. 1, 2017 to Aug. 31, 2019 via the Japan Society for Menopause and Women's Health.
- Geoffrey T. Fong has served as an expert witness or consultant for governments defending their country's policies or regulations in litigation.
- Geoffrey T. Fong and Shannon Gravely served as paid expert consultants to the Ministry of Health of Singapore in reviewing the evidence on plain/standardized packaging.
- K. Michael Cummings has served as a paid expert witness in litigation against cigarette manufacturers in the United States.
- All other authors including the presenter have no conflict of interests to declare.

Funding sources:

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ITC Japan: Transitions of people who smoke cigarettes only and people who dual use HTPs-cigarettes (2018-19)



How does consumption change when people transition from (1) cig-only to dual, and (2) dual to cig-only & HTP-only?



- Will focus on **consumption**, but will talk about the distinction between business implications and possible public health implications.
- Key definitions for examining changes in tobacco consumption:
 - Cigarettes: Cigarettes per day (**CPD**)
 - Heated Tobacco Products: HTP sticks per day (**HPD**)*
 - Total Tobacco: $CPD + HPD = \mathbf{TPD}$

* For those who use Ploom TECH, one capsule = 4 HTP sticks

Possible directions and extent of changes in cigarette and HTP consumption over time

Tobacco Use Transition	Consumption		
	CPD	HPD	TPD (CPD+HPD)
Cig-only → Cig-only	+ or -		
Cig-only → HTP+Cig	+ or -	+	+ or -
HTP+Cig → HTP+Cig	+ or -	+ or -	+ or -
HTP+Cig → Cig-only	+ or -	-	+ or -
HTP+Cig → HTP	-	+ or -	+ or -

CPD: Cigarettes per day **HPD: Heated Tobacco sticks per day** **TPD: Total Tobacco (Cig+HTP) sticks per day**

Study Sample and Analytic Methods

Study Sample

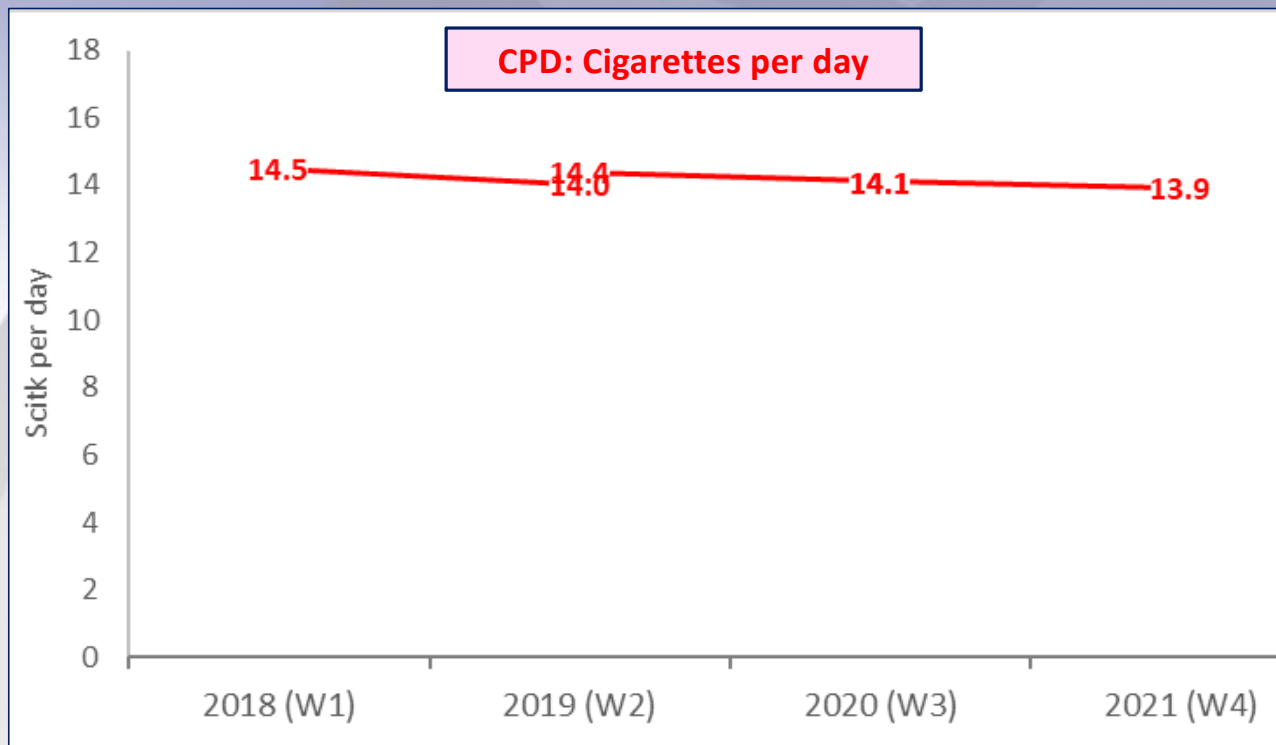
- Adults (aged ≥ 20) in 4 waves of the ITC Japan Surveys (2018-21)
- Baseline of people who smoke cigarettes only ($\geq$ weekly)
- Baseline of people who dual use HTPs-cigarettes ($\geq$ weekly for both products)
- Participated in two **consecutive** waves

Year	Cigarette-only	Dual HTP-Cigarette
2018-2019	1051	134
2019-2020	613	323
2020-2021	660	301

Analytic Methods

- Weighted longitudinal linear regression analyses examined changes in average daily tobacco consumption (cigarettes—**CPD**; HTPs—**HPD**; and TOTAL—**TPD**)

Cig-only → Cig-only

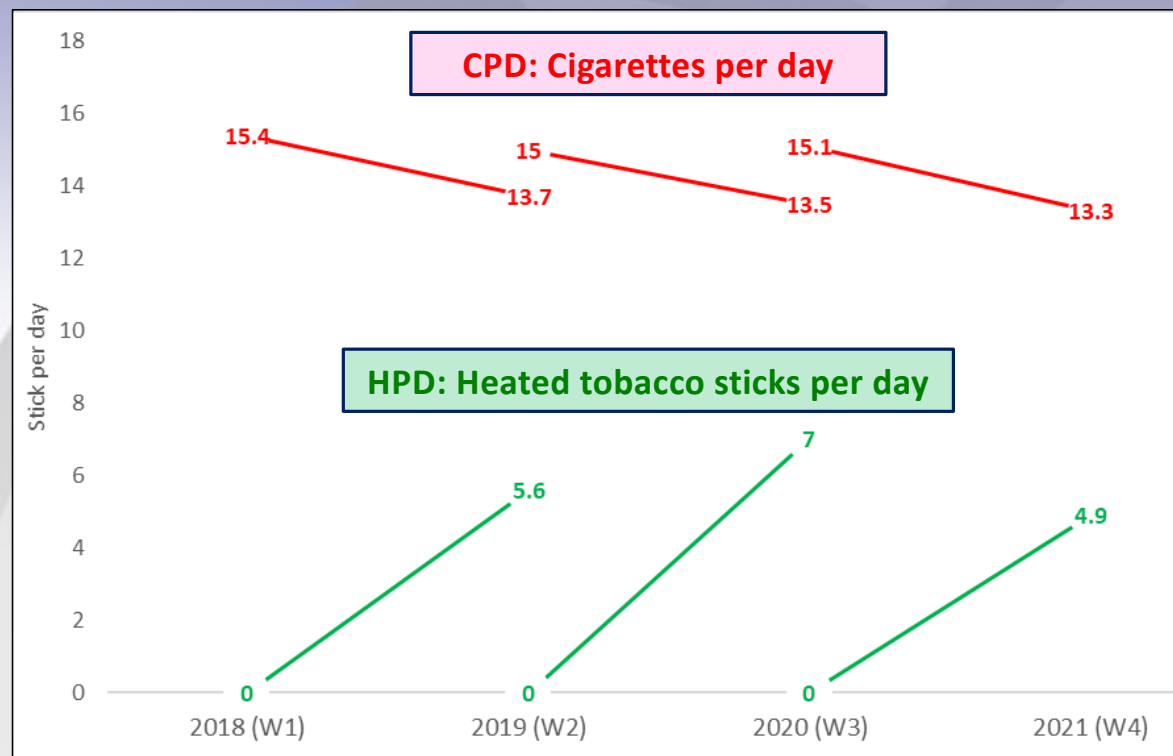


Year	Product	Difference (stick/%)
2018-2019	Cig	-0.5 (-3.4%)
	HTP	0
	Total	-0.5 (-3.4%)
2019-2020	Cig	-0.3 (-2.1%)
	HTP	0
	Total	-0.3 (-2.1%)
2020-2021	Cig	-0.2 (-1.4%)
	HTP	0
	Total	-0.2 (-1.4%)

Those who continued to exclusively smoke cigarettes:

- No change in CPD (and thus no change in TPD)

Cig-only → HTP+Cig



Year	Product	Difference (stick/%)	
2018-2019	Cig	-1.7	(-11.0%) ***
	HTP	+5.6	
	Total	+3.9	(+25.3%)
2019-2020	Cig	-1.5	(-10.0%) *
	HTP	+7.0	
	Total	+5.5	(+33.3%)
2020-2021	Cig	-1.8	(-11.9%) ***
	HTP	+4.9	
	Total	+3.1	(+20.5%)

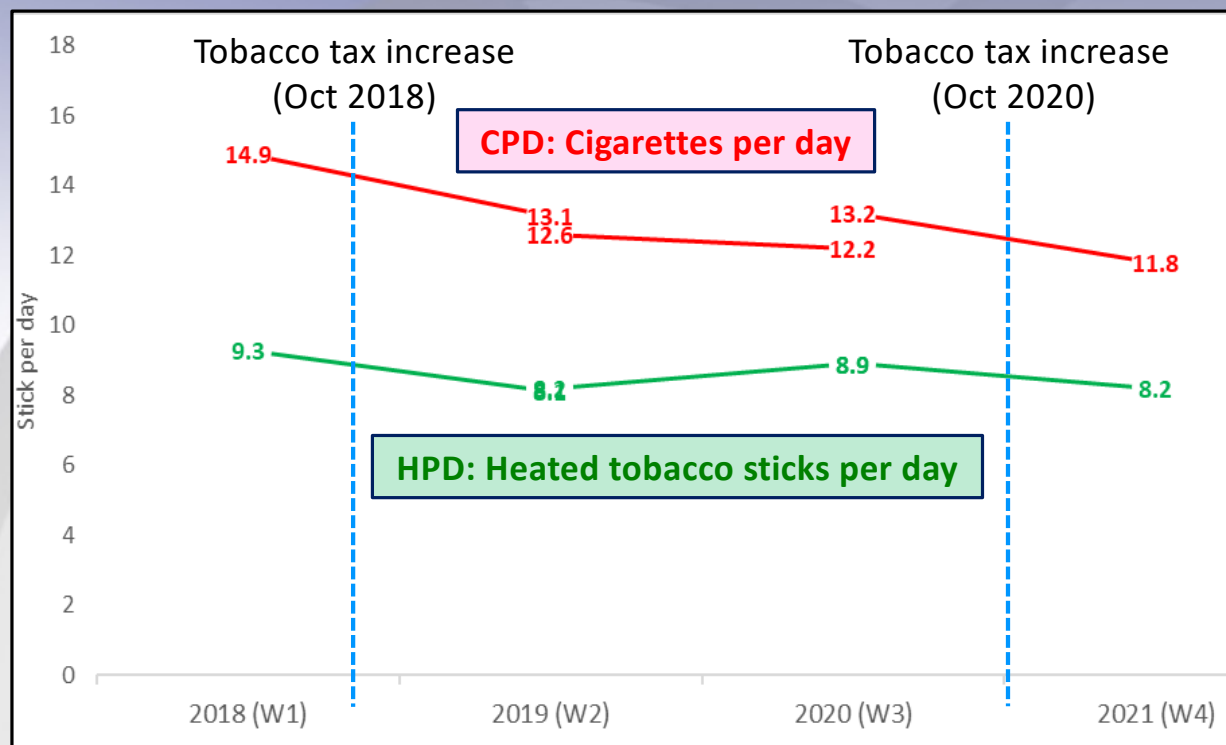
* p<0.05

*** p<0.001

Those who switched from exclusive cigarette smoking to using both cigarettes and HTPs:

- Reduced their cigarette consumption by 10-12% (-1.5 to -1.8 sticks) but added 2-4 times more HTP sticks.
- Net change = 20-33% higher total stick consumption

HTP+Cig → HTP+Cig



Year	Product	Difference (stick/%)	
2018-2019	Cig	-1.8	(-12.1%) **
	HTP	-1.2	(-12.9%)
	Total	-3.0	(-12.4%) **
2019-2020	Cig	-0.4	(-3.1%)
	HTP	+0.7	(+8.5%)
	Total	+0.3	(+3.3%)
2020-2021	Cig	-1.4	(-10.6%) *
	HTP	-0.7	(-7.9%)
	Total	-2.3	(-10.3%) **

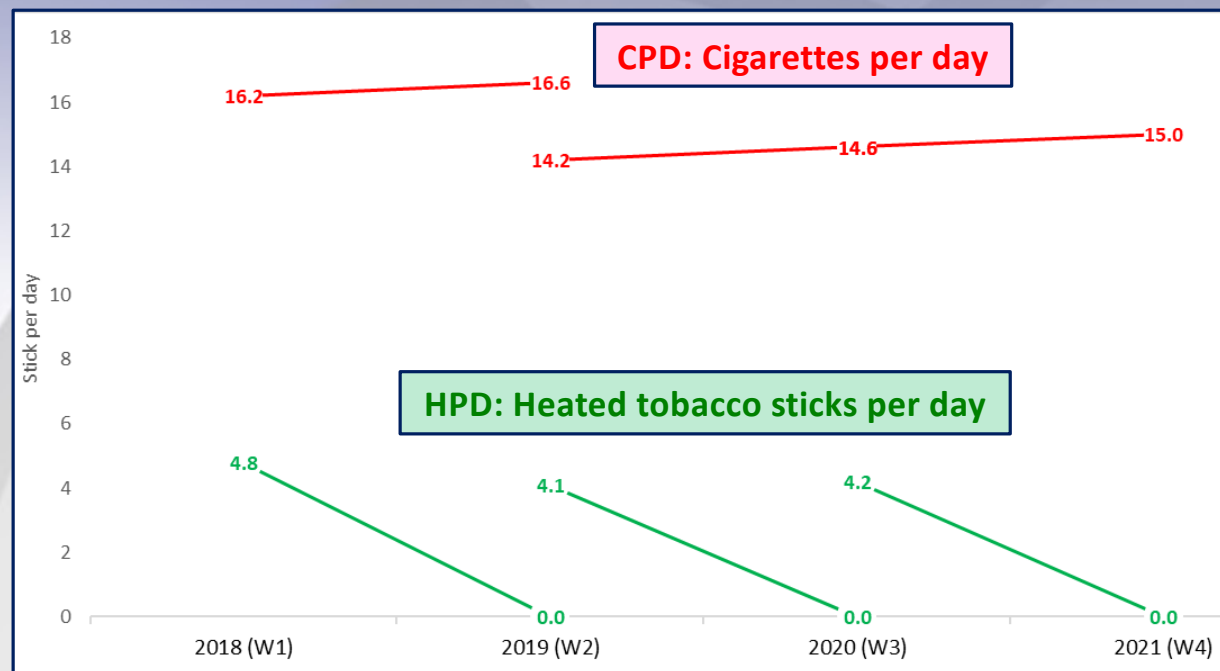
* p<0.05

** p<0.01

Those who continued to use both cigarettes and HTPs:

- Reduced both cigarettes and HTPs consumption in 2018-19 and 2020-21 (when there was a tobacco tax increase).
- But little change between 2019-20, when there was **no** tobacco tax increase.

HTP+Cig → Cig-only



Year	Product	Difference (stick/%)
2018-2019	Cig	+0.4 (+2.4%)
	HTP	−4.8
	Total	−4.4 (−21.0%) **
2019-2020	Cig	+0.4 (+2.8%)
	HTP	−4.1
	Total	−3.7 (−20.2%) **
2020-2021	Cig	+0.4 (+2.7%)
	HTP	−4.2
	Total	−3.8 (−20.8%) **

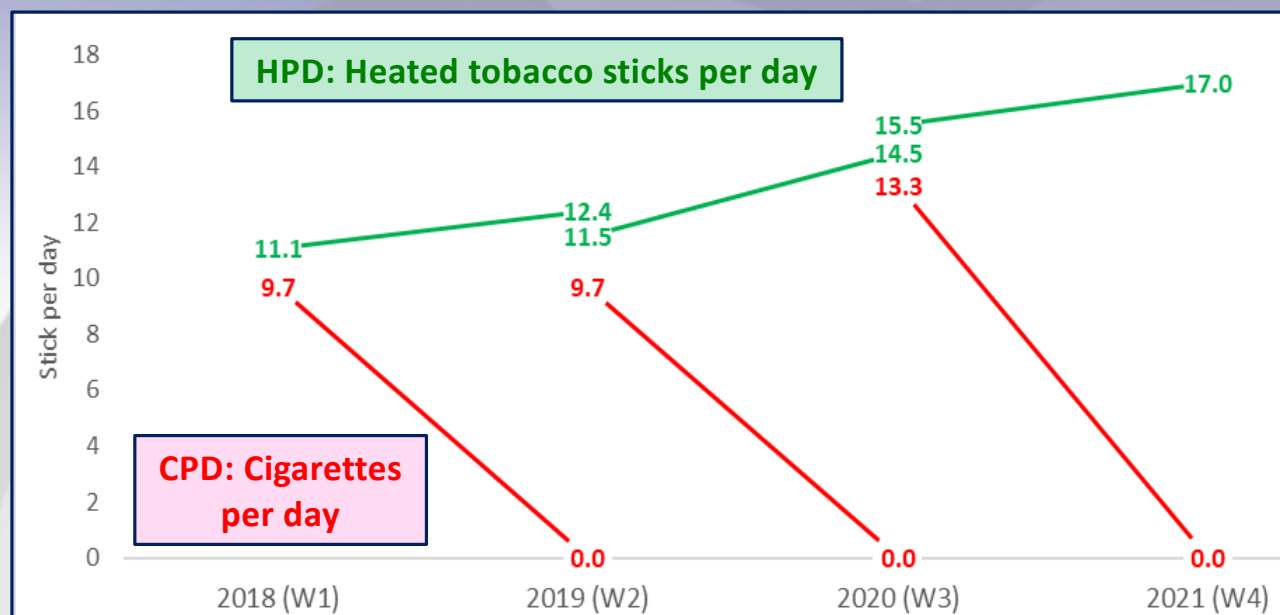
* p<0.05

** p<0.01

Those who used both cigarettes and HTPs then went (back) to cigarette-only:

- Did not increase their cigarette consumption.
- Net effect: reduction of 20% of total stick consumption

HTP+Cig → HTP-only



Year	Product	Difference (stick/%)
2018-2019	Cig	-9.7
	HTP	+1.3 (+11.7%) *
	Total	-8.4 (-40.4%) ***
2019-2020	Cig	-9.7
	HTP	+3.7 (+20.2%) ***
	Total	-6.9 (-31.1%) ***
2020-2021	Cig	-13.3
	HTP	+1.5 (+9.7%) ***
	Total	-11.6 (-40.3%) ***

* $p < 0.05$

*** $p < 0.001$

Those who used both cigarettes and HTPs then transitioned to HTP-only :

- Increased their HTP consumption by 10-20%
- Net effect: reduction of 30-40% of total stick consumption

Directions and extent of changes in tobacco consumption

Tobacco Use Transition	Consumption		
	CPD	HPD	TPD (CPD+HPD)
Cig-only → Cig-only	0		
Cig-only → HTP+Cig	-(10-12%)	++	++ (by 20-33%)
HTP+Cig → HTP+Cig	0 / -	0 / -	0 / -
HTP+Cig → Cig-only	0	--	-- (by 20-21%)
HTP+Cig → HTP-only	---	+ (10-20%)	--- (by 31-40%)

CPD: Cigarettes per day **HPD: Heated Tobacco sticks per day** **TPD: Total Tobacco (Cig+HTP) sticks per day**

Comparison of total tobacco consumption by user group from 4 cross-sectional surveys

Study	Cig-only	HTP+Cig	HTP-only
ITC Japan Survey Wave 2 (Dec 2018-Jan 2019)	14.1	20.8	16.0
Japan TMCS (Apr 2018-Jun 2019)	16.6	23.4	15.7
PMI IQOS User Survey Year 1 (Dec 2016-July 2017)	NA	24.8	16.8
JT Ploom TECH User Survey (Dec 2018)	16.2 *	20.1	18.8

* Reported CPD before taking up Ploom TECH (PT); 1 Ploom TECH tobacco capsule = 4 HTP sticks

Summary and Conclusion

When people transition from cigarettes TO dual use:

...They add HTP sticks by a much greater number than they reduce cigarettes, resulting in an average of **26% increase in total consumption.**

When people transition AWAY from dual use:

...**Back to cigarettes only (common)**: they add cigarette sticks by a lower number than they reduce HTP sticks, resulting in an average of **21% decrease in total consumption.**

...**To HTPs only (rare)**: they add HTPs by a lower number than they reduce cigarettes, resulting in an average of **37% decrease in total consumption.**

Business conclusion: Dual use is a substantial benefit for companies who produce both cigarettes and HTPs.

Potential public health consequences?

- Not clear because we are missing a key element:
the relative harmfulness of HTP sticks vs. cigarettes.

- Consider the average consumption change for those transitioning from cig-only to cig+HTP:

Cigs: -1.7 sticks

HTPs: +5.8 sticks

HTP/cig ratio = $5.8/1.7 = 3.4$

- Simple heuristic^{**}: if the harmfulness of cigarettes relative to HTPs exceeds 3.4, then the decrease of 1.7 cigs may decrease risk more than the increase of 5.8 HTP sticks increases risk. The net effect would be a reduction in risk.

Year	Product	Difference (stick/%)
2018-2019	Cig	-1.7 (-11.0%) ***
	HTP	+5.6
	Total	+3.9 (+25.3%)
2019-2020	Cig	-1.5 (-10.0%) *
	HTP	+7.0
	Total	+5.5 (+33.3%)
2020-2021	Cig	-1.8 (-11.9%) ***
	HTP	+4.9
	Total	+3.1 (+20.5%)
* p<0.05 *** p<0.001		

Public Health Conclusion: Transitioning from Cig-Only to Dual use may or may not constitute a less harmful state, depending on the relative harmfulness of HTPs vs. cigarettes.

^{**} Simple because there is certainly a non-linear (log) relationship between consumption and harmfulness.

Major Support for the ITC Project



US National Cancer Institute
P01 CA200512



Canadian Institutes of Health Research
FDN-148477



Ontario Institute for Cancer Research
Senior Investigator Award (2007-2027)

ITC Project Research Organizations



ITC Project Research Support



EXHIBIT 4

AN EXAMINATION OF PHILIP MORRIS INTERNATIONAL'S ESTIMATE OF KOREAN ADULTS WHO HAVE “COMPLETELY TRANSITIONED” FROM CIGARETTES TO IQOS: FINDINGS FROM THE 2020 AND 2021 ITC KOREA SURVEYS

Shannon Gravely¹, Gang Meng¹, Mi Yan¹, Steve S. Xu¹, Hong Gwan Seo², Sungkyu Lee³,
Sung-il Cho⁴, Yeol Kim², Gil-yong Kim⁵, Sujin Lim⁵, Su Young Kim⁵, Anne C.K. Quah¹, K.
Michael Cummings⁶, Andrew Hyland⁷, Geoffrey T. Fong^{1,8}

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Society for Research on Nicotine and Tobacco Annual Meeting
March 20-23, 2024, Edinburgh Scotland
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Presenter's affiliation(s) and disclosures



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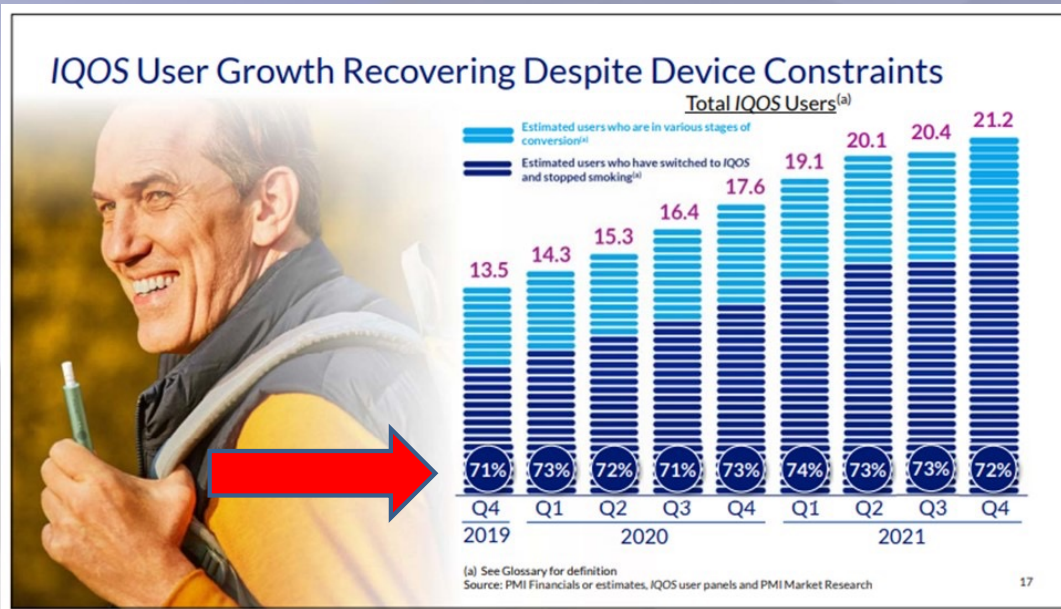
Disclosures of Interests:

- SG, SSX, GM, GTF, ACKQ, MY are supported by grants from the US National Cancer Institute (P01 CA200512) and the Canadian Institutes of Health Research (FDN-148477).
- Geoffrey T. Fong has served as an expert witness or consultant for governments defending their country's policies or regulations in litigation.
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- All other authors including the presenter have no conflict of interests to declare.

Funding:

- The ITC Korea Survey was supported by grants from the Korean Health Promotion Fund and the Canadian Institutes of Health Research Foundation Grant (FDN-148477).
- Core support for the overall ITC Seven Country Nicotine Product Survey was provided by the US National Cancer Institute (P01 CA200512) and the Canadian Institutes of Health Research (FDN-148477).
- Additional support to GTF is provided by a Senior Investigator Grant from the Ontario Institute for Cancer Research and the Canadian Cancer Society O. Harold Warwick Prize.

Have IQOS consumers stopped smoking?



Data source: IQOS user panels and PMI Market Research

PMI Definition:

Quit smoking and switched to IQOS: $\geq 95\%$ of daily tobacco consumption is IQOS

PMI reports that in their ***IQOS user sample*** panels, the percentage of customers who had quit smoking and switched to IQOS:

➡ 71-74% in 2020 & 2021

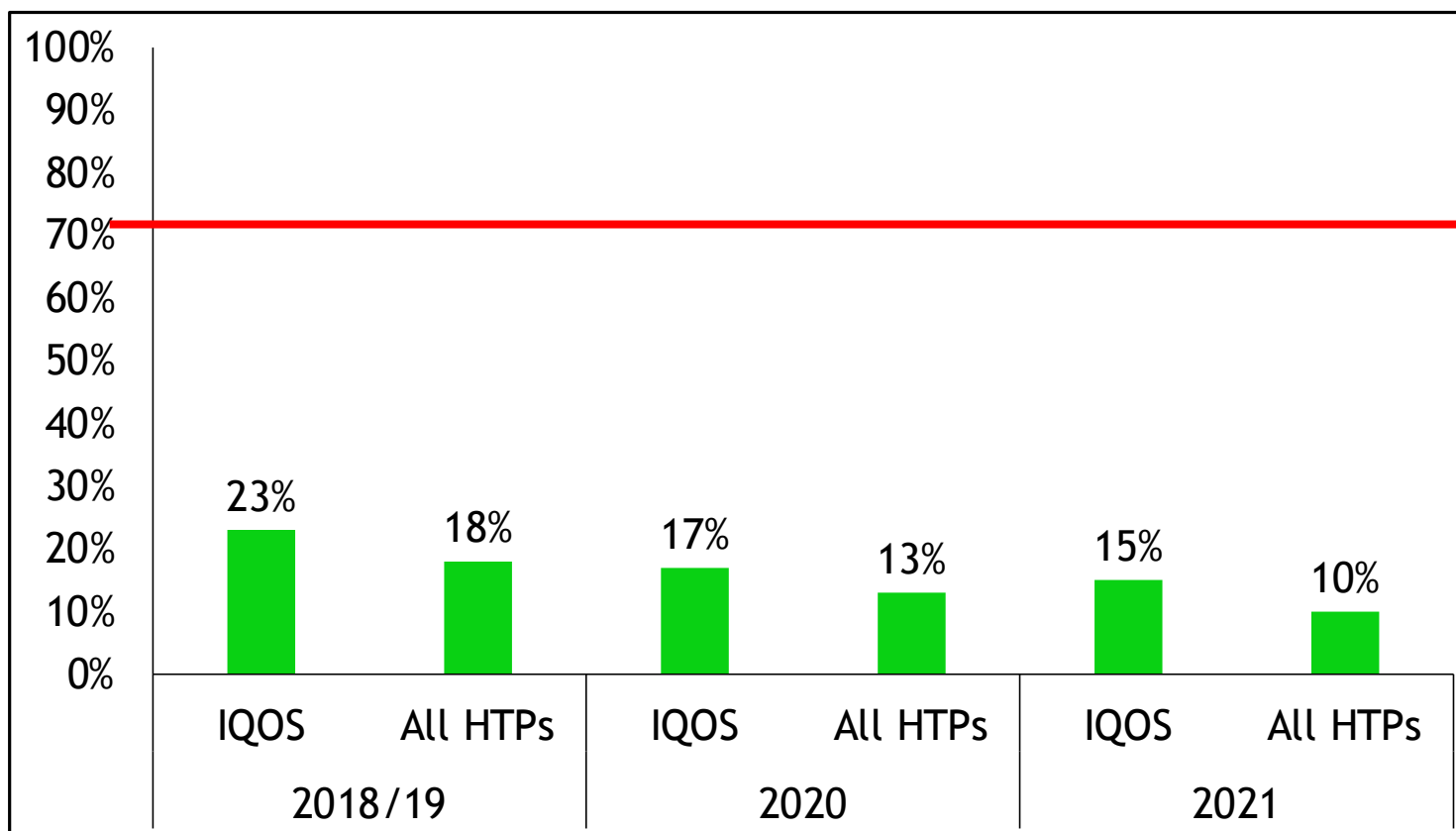
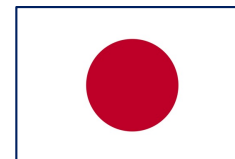
METHODS: PMI IQOS user panel in Japan



- Online (cross-sectional) survey of IQOS customers in Japan
- Purchased IQOS and agreed to participate in research
- Used IQOS in the past 30 days
- Aged 20+ years
- 100 HTP sticks in their lifetime
- 98% had a smoking history at the time of purchase
- ~2000 respondents each year (500/quarter)

Fischer et al., Trends in prevalence and patterns of use of a heated tobacco product (IQOS™) in Japan: A three-year repeated cross-sectional study, F1000Research 2022, 11:720)

Percentage of Japanese adults using HTPs who have quit smoking cigarettes: 2018-2021 ITC Japan Surveys



PMI IQOS users:
70-74% have
quit smoking



Republic of Korea



- We extended our study to the Republic of Korea:
 - 4th largest global HTP market
 - HTPs used by those with similar sociodemographics to Japan
 - Both HTPs and e-cigarettes are legal
- IQOS most commonly used HTP among adults (56%: ITC Japan Survey data)

Study Objectives



1. Using cross-sectional national data from two waves of the ITC Korea Surveys, we estimated the % of adults who regularly use HTPs and who have quit smoking cigarettes:
 - Among those using IQOS
 - Among those using the leading HTP brands: IQOS, lil, Ploom, & glo
2. Compare ITC % of HTP users who have quit smoking to those of PMI's IQOS user sample (panel surveys)





METHODS: ITC Korea Survey



In 2020, 1099 respondents (ages 19+) were using HTPs $\geq$ weekly (IQOS: n = 609)

In 2021, 1220 were using HTPs at least weekly (IQOS: n = 652)

All were smoking cigarettes or had quit smoking at the time of the survey

Used 100 HTP sticks (or equivalent) in their lifetime

Daily tobacco consumption was adopted from PMI's Stakeholder reports: IQOS account for $\geq 95\%$ of daily tobacco consumption (HTPs + cigarettes per day)*

**Calculated using ITC KRA weighted data based on the age*sex distribution of PMI's Japan IQOS User Surveys (PMI Korea data are not available), thus aligning our weighted estimates with PMI's own estimates as closely as possible with publicly available information*

Corresponding survey dates used for this study: ITC Korea Surveys and PMI IQOS user sample surveys



ITC Korea Surveys

PMI Reports Year: Quarter

Wave 1: June 19 to 28, 2020

2020: Q2 IQOS user sample

Wave 2: Nov 3 to Dec 13, 2021

2021: Q4 IQOS user sample

Analyses of the ITC Korea Survey data

- Cross-sectional weights were original ITC weights (Korea Community Health Survey as the benchmark) recalibrated to PMI's sex* age distribution.
- This adjusts the ITC data so that matches the sex * age distribution of the PMI surveys

Daily tobacco consumption[†] =
Cigarettes + HTPs* =
HTPs/Cigarettes + HTPs

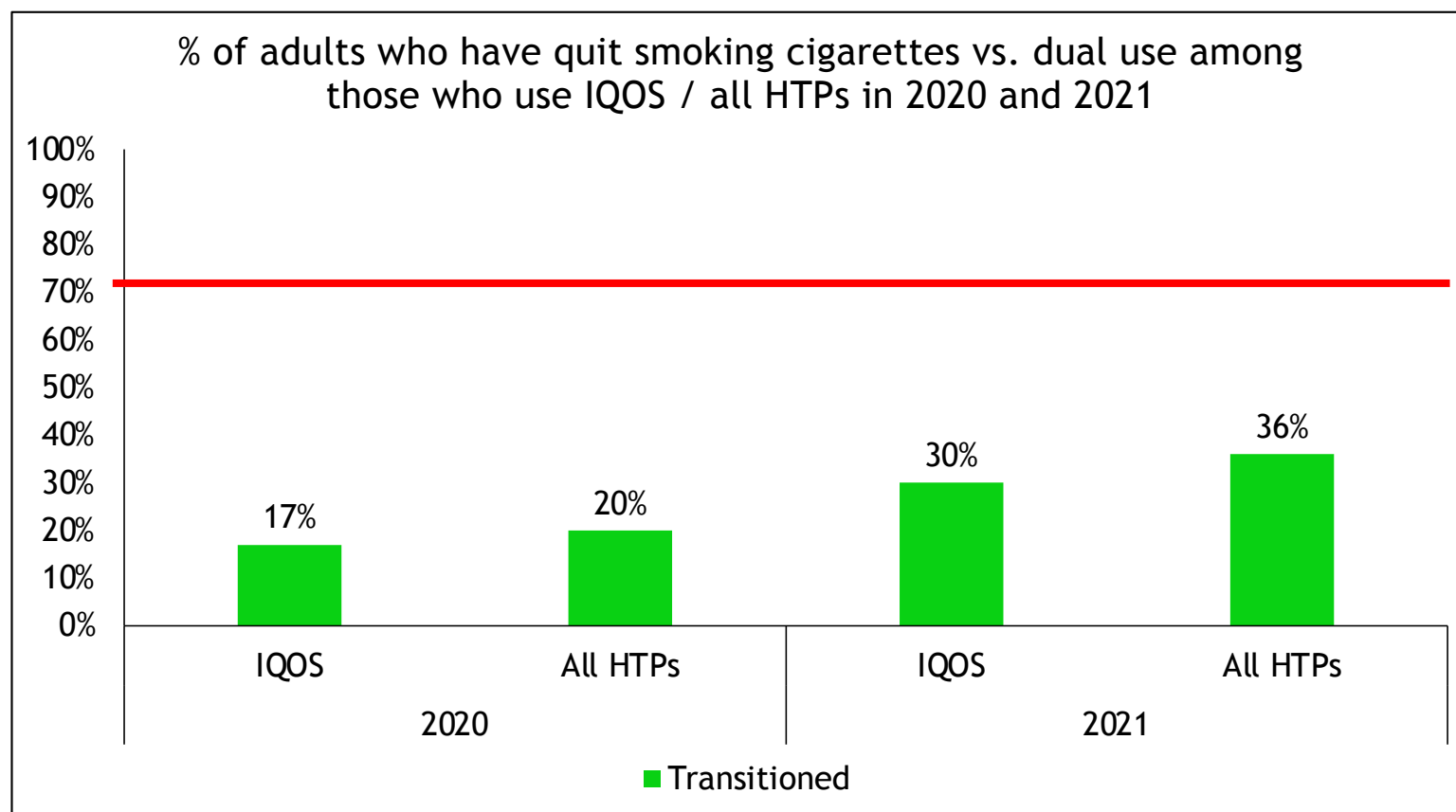


Cumulative distribution from 5% to
100%
Quit smoking = ≥95% HTPs

HTPs: Heat sticks or equivalent # capsules; † daily tobacco consumption did not include other nicotine/tobacco products



Transition rates did not differ between people who vaped nicotine vs. those who did not (all $p>0.5$).



PMI IQOS users:
70-74% have
quit smoking

Quit smoking = the proportion of HTP consumers who's daily HTP and cigarette tobacco consumption was $\geq 95\%$ HTPs

Summary and Conclusion

- Most Korean adults regularly using IQOS and/or other HTPs did not quit smoking; rather, they had high rates of dual use.
- These results in Korea replicate our findings in Japan in 2020; but higher in 2021 in Korea
- Large discrepancy between the ITC data and the PMI data on the percentage of IQOS consumers who have quit smoking and switched to IQOS: ITC percentages were much lower.
- Are HTP consumers using HTPs to quit?
 - Seo et al. ITC publication: reasons for using HTPs: 35.4% Korean adults use HTPs because HTPs might help them quit. 49.7% for other reasons besides quitting or reducing smoking (Seo et al. IJERPH, 2023, 11;20(6):4963).
- **These findings highlight the importance of non-industry research on measuring and understanding use patterns of HTPs, particularly how HTPs interact with cigarettes.**

itc
International Tobacco Control
Policy Evaluation Project



(19/641)

UNIVERSITY OF WATERLOO ROSWELL PARK MUSC KINGS LONDON THE UNIVERSITY OF QUEENSLAND VTC Virginia Tech Carilion School of Medicine and Research Institute

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UNIVERSITY OF MALAYA INCA verian Maastricht University KHEPI Korea Health Promotion Institute 国立がん研究センター National Cancer Center Japan Nederland Rookvrij aerport

국립암센터 NATIONAL CANCER CENTER ERS ERS NYU UTM Santé publique France American Society MAURITIUS INSTITUTE OF HEALTH

Salut ICO UNIVERSITY OF OXFORD European Network for Smoking and Tobacco Prevention Abu Dhabi dkfz Ciet UNIVERSIDAD DE LA REPUBLICA

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NIH NATIONAL CANCER INSTITUTE

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NHMRC

MINISTRY OF HEALTH

보건복지부 Ministry of Health and Welfare

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国立がん研究センター

National Cancer Center Japan

Hartstichting

국립암센터

NATIONAL CANCER CENTER

Unión Europea

EXHIBIT 5

Funding: This study was supported by a grant from the Korean Ministry of Health and Welfare and the Canadian Institutes of Health Research (FDN-147488). Additional support to GTF was provided by a Senior Investigator Award from the Ontario Institute for Cancer Research. The funders had no role in the design and conduct of the study, data collection, management, analyses, interpretation of the data, or the preparation of this presentation.

Disclosures: GTF has served as an expert witness or consultant for governments defending their country's policies or regulations in litigation. KMC has in the past and continues to serve as a paid expert witness in litigation filed against cigarette manufacturers. All other authors have no conflicts of interest to declare.

TRANSITIONS BETWEEN CIGARETTES AND HEATED TOBACCO PRODUCTS AMONG ADULTS WHO USE VS DO NOT USE NICOTINE VAPING PRODUCTS IN THE REPUBLIC OF KOREA: FINDINGS FROM THE 2020, 2021, AND 2023 ITC KOREA SURVEYS

Geoffrey T. Fong^{1,2}, Gang Meng¹, Shannon Gravely¹, Mary E. Thompson¹, Steve S. Xu¹, Anne C.K. Quah¹, Hong Gwan Seo^{3,4}, Sungkyu Lee⁵, Su Young Kim⁶, Gil-yong Kim⁶, Sujin Lim⁶, Sung-II Cho^{7,8}, K. Michael Cummings⁹, Andrew Hyland¹⁰

¹University of Waterloo, Canada, ²Ontario Institute for Cancer Research, Canada, ³Korea National Cancer Center, Republic of Korea, ⁴Graduate School of Cancer Science and Policy, National Cancer Center, Republic of Korea, ⁵Korea Center for Tobacco Control Research and Education, Republic of Korea, ⁶Korea Health Promotion Institute, Republic of Korea, ⁷Seoul National University, Republic of Korea, ⁸Graduate School of Public Health, Seoul National University, Republic of Korea, ⁹Medical University of South Carolina, USA, ¹⁰Roswell Park Comprehensive Cancer Center



Number: POS04-121
Date: Fri 3/22/2024
Time: 5:30-7:00pm

BACKGROUND

- The Republic of Korea is the world's 4th largest market for heated tobacco products (HTPs). In Korea, HTPs are regulated at the same level as cigarettes. It is important to understand how HTPs interact with cigarettes.
- We previously examined transitions of HTPs to/from cigarettes in Japan, the world's largest HTP market, finding that HTPs were not associated with smoking cessation but instead with long-term dual use.
- Korea differs from Japan in that nicotine vaping products (NVPs) are legal. The nicotine market in Korea is thus more similar to the nicotine market in the United States and other countries. It is important to understand interactions among the three products.

OBJECTIVES

- Among a national sample of Korean adults—to examine transitions between states of tobacco product use (cigarette only, HTP only, dual use, former smokers who do not use HTPs) across consecutive waves.
- To examine specifically if HTP use is associated with transitions away from smoking.
- To examine whether transitions differed for those who also used NVPs vs. those who did not use NVPs. This can be tested in Korea but not in Japan, where NVPs are banned.

METHODS

- Data came from Waves 1-3 (2020, 2021, 2023) of the ITC Korea Surveys, national cohort surveys of adults (19+ years). The dataset consisted of respondents who participated in at least 2 of the 3 waves. Wave 1 cohort: N = 1696; Wave 2 cohort: N = 1073
- We employed a Markov multi-state (MSM) model to examine transitions in use of cigarettes and HTPs over each wave. MSM treats time as a continuous variable—more realistic since there were interwave interval differences; other modeling approaches treat time as discrete.
- Four states of tobacco product use:
 - Those who smoked cigarettes but did not use HTPs $\geq$ weekly (**Cig only**)
 - Those who used HTPs but did not smoke $\geq$ weekly (**HTP only**)
 - Those who smoked and used HTPs $\geq$ weekly (**Cig+HTP Dual**)
 - Those who quit cigarettes and who did not use HTPs or used HTPs < weekly (**No Cig/HTP**)
- Analyses were weighted. Sex, age, and initial NVP status were covariates.
- We also examined whether vaping was associated with different transition patterns:
 - Those who also vaped: N=385
 - Those who did not also vape: N=2384

RESULTS

Transition Tables

- In these tables, we present the MSM estimates of one-year cumulative transition probabilities for each pre-transition state. MSM takes into account the actual time interval between waves.
- In the top transition table (All Respondents), sex, age, and initial NVP status were covariates.
- The bottom two transition tables present the transitions by whether they were or were not vaping at the initial wave. The transitions for the HTP only and No Cig/HTP groups did not include sex and age as covariates due to low sample size.
- Statistical tests employed standard errors estimated by bootstrapping.

All Respondents

Pre-Transition State	Post-Transition State %				
	Cig Only	Dual	HTP only	No Cig/HTP	Non-smoking
Cig only N=2155	86.1 (85.0, 87.2)	8.2 (7.4, 9.1)	0.3 (0.2, 0.3)	5.4 (4.5, 6.3)	5.7
Cig+HTP dual N=1467	11.4 (9.4, 13.5)	85.0 (81.8, 88.1)	3.0 (1.9, 4.2)	0.6 (-1.3, 2.5)	3.6
HTP only N=128	5.0 (3.8, 6.3)	58.9 (49.1, 68.7)	30.8 (20.8, 40.8)	5.3 (1.5, 9.2)	36.1
No Cig/HTP N=188	11.0 (6.3, 15.7)	2.4 (1.3, 3.5)	2.9 (1.0, 4.7)	83.8 (78.1, 89.5)	86.7

- For three groups, >80% did not transition over time. The exception was HTP only: only 31% stayed in that state, and they were much more likely to transition (back) to smoking.
- Cig only:** 8.5% of them initiated HTPs, but nearly all of them (8.2/8.5 = 96.5%) were still smoking at the next wave (i.e., they were dual using).
- Dual use:** they were not less likely than Cig only to have quit cigarettes: 3.6% vs. 5.7% (p=0.10), but they were much less likely than Cig only to have quit both cigarettes and HTPs: 0.6% vs. 5.4%. (p<0.001).
- Future transition analyses will be conducted starting with those who exclusively smoke at Wave 1, and then start the analysis of transitions at Wave 2.

Those using HTPs who vaped at initial wave

Pre-Transition State	Post-Transition State %				
	Cig Only	Dual	HTP only	No Cig/HTP	Non-smoking
Cig only + NVP N=133	79.0 (73.4, 84.6)	12.8 (8.6, 16.9)	0.4 (0.2, 0.6)	7.8 (4.3, 11.4)	8.2
Cig+HTP dual + NVP N=342	6.4 (4.4, 8.3)	90.1 (87.1, 93.0)	3.1 (1.4, 4.8)	0.5 (-0.6, 1.6)	3.6
HTP only + NVP N=22	3.8 (1.6, 4.1)	39.1 (23.9, 54.3)	37.9 (19.6, 56.2)	19.2 (4.9, 33.5)	57.1
No Cig/HTP + NVP N=43	17.6 (10.7, 24.5)	2.1 (1.1, 3.2)	1.0 (-0.3, 2.3)	79.2 (71.2, 87.2)	80.2

- For those using HTPs who vaped at initial wave: Similar transition pattern
- Cig only who took up HTPs (13.2%): 12.8/13.2 = 97% dual use
- Dual use: less likely to have quit smoking than cig only (3.6% vs. 8.2%) (p = 0.01)

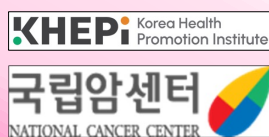
Those using HTPs who did NOT vape at initial wave

Pre-Transition State	Post-Transition State %				
	Cig Only	Dual	HTP only	No Cig/HTP	Non-smoking
Cig only & No NVP N=2022	86.8 (85.7, 87.9)	7.7 (6.8, 8.5)	0.3 (0.2, 0.3)	5.3 (4.4, 6.2)	5.6
Cig+HTP dual & No NVP N=1125	12.2 (9.8, 14.5)	84.2 (80.8, 87.7)	3.0 (1.8, 4.2)	0.6 (-1.4, 2.6)	3.6
HTP only & No NVP N=106	5.3 (3.8, 6.7)	59.3 (49.1, 69.5)	31.3 (20.3, 42.3)	4.1 (1.6, 6.6)	35.4
No Cig/HTP & No NVP N=145	10.8 (5.9, 15.7)	2.3 (1.2, 3.4)	2.8 (0.8, 4.7)	84.1 (78.3, 89.9)	86.9

- For those using HTPs who did NOT vape at initial wave: Similar transition pattern
- Cig only who took up HTPs (8.0%): 7.7/8.0 = 96% dual use
- Dual use: no more likely to have quit smoking than cig only (3.6% vs. 5.6%) (p = 0.14)

CONCLUSIONS

- Transitions to/from cigarettes and HTPs in Korea were similar to transitions we previously found in Japan: when those who smoke took up HTPs, there were low rates of transitioning away from cigarettes.
- HTP use was not associated with smoking cessation but with a very high percentage of HTP-cigarette dual use (>95%).
- NVP use was a partial moderator: although cig only who also vaped were more likely to transition to HTPs overall (p = 0.02), NVPs did not moderate transitions to not smoking. In other words, NVPs and HTPs were substitutes, but neither was associated with transitions away from smoking.
- Studies of HTP emissions and biomarkers of exposure show that although HTPs are not harmless, they expose consumers to lower levels of most toxicants than cigarettes, but higher than NVPs (e-cigarettes).
- The impact of HTPs on public health depends on the extent to which HTPs increase smoking cessation.
- This ITC Korea study is consistent with the ITC Japan study: suggesting that HTPs may not help increase transitions towards quitting smoking.



Society for Research on Nicotine and Tobacco Annual Meeting
March 20-23, 2024, Edinburgh, Scotland
Contact: Geoffrey T. Fong
(gafong@uwaterloo.ca)
Website: <https://itcproject.org/>

Core Support provided by the Republic of Korea National Health Promotion Fund
Core Support provided by the U.S. National Cancer Institute (P01 CA200512)
Core Support provided by a Canadian Institutes of Health Research Foundation Grant (FDN-148477)



EXHIBIT 6



Changes in Cigarette and Total Tobacco Consumption among Korean Adults When Transitioning between Exclusive Cigarette Smoking and Dual Use of Cigarette and Heated Tobacco Products: Findings from the 2020-2023 ITC Korea Surveys

Steve S. Xu^{1*}, Gang Meng¹, Mi Yan¹, Shannon Gravely¹, Hong Gwan Seo², Sungkyu Lee³, Sung-il Cho⁴, Yeol Kim², Su Young Kim⁵, Gil-yong Kim⁵, Sujin Lim⁵, Anne C. K. Quah¹, K. Michael Cummings⁶, Andrew Hyland⁷, Geoffrey T. Fong^{1, 8}

¹University of Waterloo, Canada; ²National Cancer Center, Republic of Korea; ³ Korea Center for Tobacco Control Research and Education;

⁴Seoul National University, Republic of Korea; ⁵Korea Health Promotion Institute; ⁶Medical University of South Carolina, USA;

⁷Roswell Park Comprehensive Cancer Center, USA; ⁸Ontario Institute for Cancer Research, Canada



**Presented at Society for Research on Nicotine and Tobacco
30th Annual Meeting, March 23, 2024
Edinburgh, Scotland
*Contact: s4xu@uwaterloo.ca**



None of the authors report any support from tobacco, nicotine, or pharmaceutical companies in the past 5 years, and this study was not funded by such companies

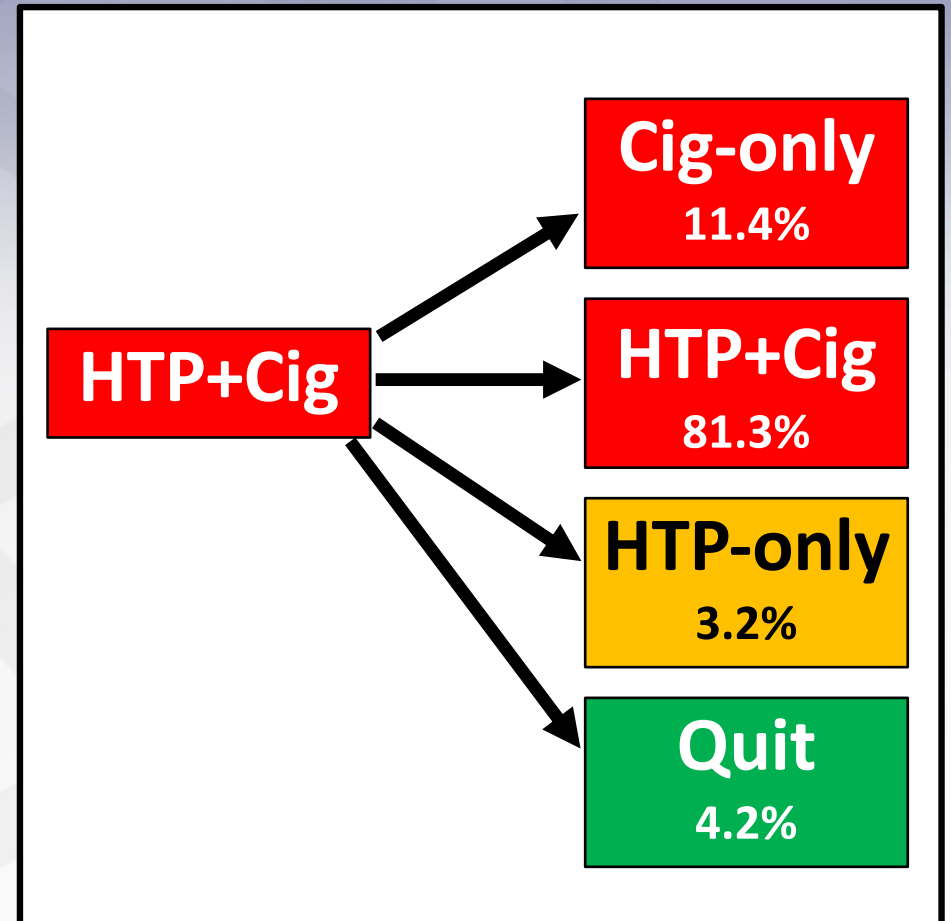
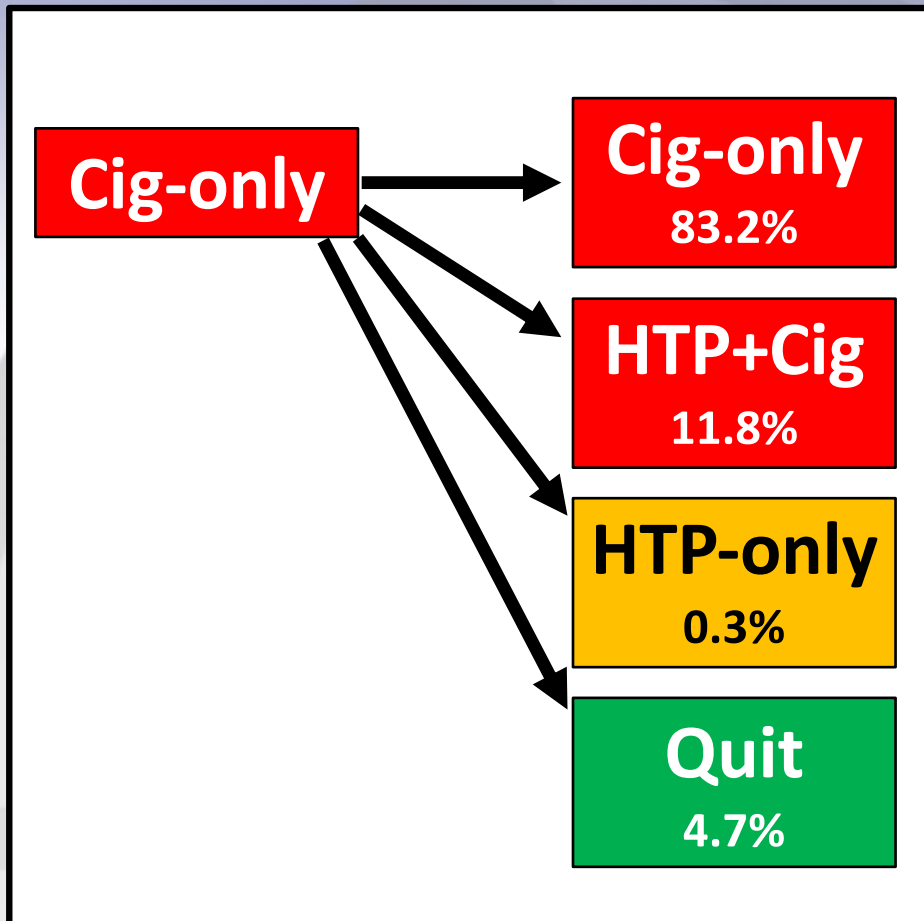
Disclosures of Interests:

- Geoffrey T. Fong has served as an expert witness or consultant for governments defending their country's policies in litigation.
- Geoffrey T. Fong and Shannon Gravely served as paid expert consultants to the Ministry of Health of Singapore in reviewing the evidence on plain/standardized packaging.
- K. Michael Cummings has served as a paid expert witness in litigation against cigarette manufacturers in the United States.

Funding:

- The **ITC Korea Survey** was supported by grants from the Korean Health Promotion Fund and the Canadian Institutes of Health Research (FDN-148477).
- Core support for the **overall ITC Seven Country Nicotine Product Survey** was provided by the US National Cancer Institute (P01 CA200512) and the Canadian Institutes of Health Research (FDN-148477)
- Additional support to GTF was provided by a Senior Investigator Grant from the Ontario Institute for Cancer Research, Senior Prevention Scientist Award from the Canadian Cancer Society Research Institute, and the Canadian Cancer Society O. Harold Warwick Prize.

ITC Korea: Transitions of people who smoke cigarettes only and people who dual use HTPs-cigarettes (2020-21)



Research questions

1. How does tobacco consumption change when people transition from (1) cig-only to dual (cig+HTP); (2) dual to cig-only; (3) dual to HTP-only

Measures of consumption

Cigarettes:	Cigarettes per day (CPD)
HTPs:	Heated tobacco sticks per day (HPD)*
Total Tobacco:	$CPD + HPD = \mathbf{TPD}$

* For those who use Ploom TECH, one capsule = 4 heated tobacco sticks

* For those who use glo sens, one capsule = 6.3 heated tobacco sticks

2. In Korea, unlike in Japan, nicotine vaping products (NVPs; e-cigarettes) are legal. Does vaping change the pattern of consumption change when people transition to/from dual use?

Study Sample and Analytic Methods



- **Study Source and Sample:**

- ITC Korea Survey, national web panel cohort survey (total N~4700).
 - Adults (≥ 19 yrs) who smoke and/or recently quit, and/or use HTPs and/or NVPs
 - Wave 1: 2020 (N=4740), Wave 2: 2021 (N=4467), Wave 3: 2023 (N=4769)
- Followed two groups from baseline wave to followup (2020 to 2021; 2021 to 2023)

- Those who smoke cigarettes only ($\geq$ weekly)
 - Those who dual use cigarettes & HTPs ($\geq$ weekly)
- Measured the consumption of cigarettes and HTPs before/after transitions

Baseline-Followup	Cigarette Only	Dual HTP-Cigarette
2020 – 2021	975	604
2021 – 2023	1184	865

- **Analytic Methods:** Weighted longitudinal linear regression analyses of changes in average daily tobacco consumption: CPD, HPD, TPD

Cigarettes only → Cigarettes + HTPs (dual use)(12%)

Tobacco Consumption	Baseline	Followup	Diff	% Diff	Test of diffs
Cigarettes/day (CPD)	13.3	12.7	-0.6	-6.0%	W1-W2: n.s. W2-W3: n.s.
Heat sticks/day (HPD)	0	6.4	+6.4		
Total sticks/day (TPD)	13.3	19.1	+5.8	+43.6%	W1-W2: p<0.001 W2-W3: p<0.001

- Very slight reduction in cigarettes, but large addition of HTP sticks
- When those who only smoke cigarettes add HTPs to dual use, their total tobacco stick consumption increases by 44%.

Does vaping change the consumption pattern from exclusive smoking to dual use?

All who changed from
exclusive smoking to dual use

Tobacco	Baseline	Followup	Diff
Cigs/day	13.3	12.7	-0.6
HTPs/day	0	6.4	+6.4
Total/day	13.3	19.1	+5.8

Those who vaped at baseline and/or followup

Tobacco	Baseline	Followup	Diff
Cigs/day	9.8	9.3	-0.5
HTPs/day	0	5.0	+5.0
Total/day	9.8	14.3	+4.5

Those who did NOT vape

Tobacco	Baseline	Followup	Diff
Cigs/day	14.4	13.7	-0.7
HTPs/day	0	6.6	+6.6
Total/day	14.4	20.3	+5.9

- Those who also vaped: much lower stick consumption (getting nicotine from vaping)
- Vaping does not change the basic pattern of changes in consumption.

HTP+Cigarette Dual use → Cigarette only (11%)

Tobacco Consumption	Baseline	Followup	Diff	% Diff	Test of diffs
Cigarettes/day (CPD)	13.7	11.2	-2.5	-18.2%	W1-W2: p=.02 W2-W3: p=.02
Heat sticks/day (HPD)	6.0	0	-6.0	-100%	
Total sticks/day (TPD)	19.7	11.2	-8.5	-43.1%	W1-W2: p<.001 W2-W3: p<.001

- Cigarettes do NOT increase; rather they also decrease (significantly)
- This was consistent for both wave transitions (W1-W2 and W2-W3)
- When those who dual use cigarettes and HTPs go back to cigarettes only, their total tobacco stick consumption decreases by 43%.

Does vaping change the consumption pattern from dual use back to exclusive smoking?

We could not examine the impact of vaping for consumption changes for dual use to exclusive smoking since there were only 8 respondents who made this transition who also vaped.

Cigarette-HTP dual use → HTP only (3%)

Tobacco Consumption	Baseline	Followup	Diff	% Diff	Test of diffs
Cigarettes/day (CPD)	9.2	0	-9.2	-100%	
Heat sticks/day (HPD)	10.0	15.0	+5.0	+50%	W1-W2: n.s. (low n) W2-W3: n.s. (low n)
Total sticks/day (TPD)	19.2	15.2	-4.2	-21.8%	W1-W2: n.s. (low n) W2-W3: n.s. (low n)

- HTP sticks increased, but not as much as cigarettes decreased
- Net effect: Total consumption decreased by 22%
- Low sample size so low power for statistical tests.

Summary and Conclusions

1. When people transition from **cigarette-only** to **cigarette-HTP dual use**:
44% increase in total consumption
2. When people transition AWAY from dual use:
 - **Dual to cigarette only** (11% of duals): 43% decrease in total consumption
 - **Dual to HTP only** (3% of duals): 22% decrease in total consumption.
3. Dual use is an **apex state**: much higher total consumption than exclusive use (of cigarettes or of HTPs)
4. Same pattern of results as in Japan, but more pronounced in Korea
5. Using NVPs does not alter the basic pattern of changes in consumption.

Dual use is a substantial benefit for companies who produce both cigarettes and HTPs.

Major Support for the ITC Seven Country Nicotine Product Survey of which the ITC Korea Survey is a component



US National Cancer Institute:
P01 CA200512



Canadian Institutes of Health Research:
FDN-148477



National Health and Medical Research Council of Australia: APP1106451, GTN1198301



Ontario Institute for Cancer Research:
Senior Investigator Award (2007-2027)



Korea Health Promotion Fund — Main support for Korea Surveys



New Zealand Health Research Council
(19/641)

ITC Project Research Organizations



ITC Project Research Support





Thank you very much!
매우 감사합니다

EXHIBIT 7

IQOS and the Process of Changing to Evolve

Ever think about all the times you looked for a different way of doing things and ended up discovering something much better?

#TheChallenge

Mon June 21, 2021 08:55 AM

Message paid for by Phillip Morris

Recent times have challenged us to transform ourselves in a few short weeks: more technology, new habits, fast adaptations. It's an era of new starts, with all the opportunities that involves.

One inspirational example of change is Philip Morris. This 173-year-old company, the leader of the tobacco market, is revolutionizing its production to the point of creating a device that lays the foundations for a smoke-free future.

IQOS is an electronic device created with HeatControl™ technology that heats **real tobacco** instead of burning it. In short, it's a milestone for the industry—such that it has already been authorized by the US Food and Drug Administration (FDA) as a product of “modified risk.”

And the fact that natural tobacco is not burnt means that fewer toxic chemicals are emitted than with a traditional cigarette. This device is less bothersome to non-smokers:

- ☐ No smoke
- ☐ No fire
- ☐ No ash
- ☐ With real tobacco.

What's more, **IQOS** comes with a variety of cases, holders, and accessories in many colors.

We would like to inform the adult population that has decided not to quit cigarettes about the lower-risk

alternatives that are available in the country. This way, they will have enough information to freely and responsibly decide whether to use them.

Catalina Betancourt, Vice President of Corporate Affairs at Philip Morris Mexico.

Because in this free search for something better, the company is also promoting another important principle:

If you don't smoke, don't start. If you do smoke, quit. If you don't want to quit but want to make a change, #ChooseTheChange.

Philip Morris is offering a total transformation that will revolutionize smokers' worlds: a smoke-free future. IQOS' challenge is to live the change.

Want to learn more? Visit IQOS on Instagram @IQOS_MX and Twitter @iqos_mx



Certification of Translation Accuracy

I, Eileen Cullen, hereby certify that the document(s) included in this delivery, to the best of my knowledge and belief, are true, accurate and complete translations from **Spanish (US)** into **English (US)** of the content from the following file(s):

- IQOS y el proceso de cambio para evolucionar

Name:	Eileen Cullen
Translation Company:	Language Scientific, Inc®
Project:	139007
Date:	1/4/2024

EXHIBIT 8



PHILIP MORRIS PRODUCTS S.A.

His Excellency Alikhan Smailov
Prime Minister of the Republic of Kazakhstan

April 5, 2022

Dear Prime Minister Smailov,

I was honored to have the opportunity to meet you on March 31, 2022, and share our company's perspective on investments to localize production of next generation of innovative portfolio – our heated tobacco products in Kazakhstan. Thanks for your honest feedback and considering to provide tax incentives for the project.

At the same time I was surprised to notice that ideology seems to prevail over science and evidence when assessing these novel products. At the same time, a growing number of governments around the world recognized the health benefits of heated tobacco products, such as their reduced exposure, and the decision of the U.S. Food Drug and Administration that authorized these products as benefitting public health.

I would like to express my sincere gratitude to your proposal to establish a working group consisting of Ministries of Health, Finance, Economy, Foreign Affairs, and Philip Morris International. We stand ready to share scientific evidence proving that heated tobacco products can promote public health. We are happy to invite a delegation of your Cabinet and leading Kazakh scientists to visit our R&D center in Neuchatel, Switzerland, or alternatively bring our scientists over to Nursultan. I just ask for an objective review of the science behind our products, so that you can take an informed decision whether to have millions of Kazakhs to continue smoking or move to better alternatives.

We have expressed serious consideration of bringing investments to Kazakhstan to locally manufacture our innovative products, also with the objective to develop a hub to export them to other countries. Undoubtedly, such investment will bring diversified technological innovation to Kazakhstan, generate additional economic benefits across the entire supply chain and reaffirm our trust and intention to sustain long-term commitment to the country. Without sharing the same views on the reduced risk potential of next generation of our products and an appropriate regulatory framework investing into a manufacturing hub may not be a win-win solution for both parties.

We look forward to cooperation with the Government of Kazakhstan to make this investment happen and look forward to meet you again, as we discussed.

Sincerely,

Marco Mariotti
President Eastern Europe Region



PHILIP MORRIS PRODUCTS S.A.

- Copy: Mr. Sultangaziyev M.E., First Vice Minister of Finance
of the Republic of Kazakhstan
- Copy: Mr. Kuantirov A.S., Minister of National Economy
of the Republic of Kazakhstan
- Copy: Ms. Giniyat A.G., Minister of Health
of the Republic of Kazakhstan
- Copy: Mr. Aidarov A.A., Deputy Minister of Foreign Affairs
of the Republic of Kazakhstan
- Copy: Mr. Bozumbaev K.A., Akim of Almaty region
- Copy: Mr. Escobar, Juan Carlos, Managing Director,
Philip Morris Kazakhstan

EXHIBIT 9

Massimo Adolina, PMI: Greece's key role for a cigarette-free future

In addressing the Delphi Economic Forum, Massimo Andolina, President for Europe of Philip Morris International, spoke about the company's radical transformation, driven by science and the vision of the end of cigarettes. Source:

Protagon.gr Protagon Team MAY 11, 2023, 12:30 PM Source: Protagon.gr

"Nowadays there are alternatives. We need to evolve our thinking about tobacco, just as we have evolved our thinking in other areas of our lives."

In addressing the Delphi Economic Forum, Massimo Andolina, President for Europe of Philip Morris International, spoke about the company's radical transformation, driven by science and the vision of the end of cigarettes.

Philip Morris International has invested over 10.5 billion dollars in the last 15 years in research and development of new products, designing and developing better alternatives to cigarettes. Mr. Andolina explained that this radical transformation instilled a tremendous sense of purpose in everyone in the company. Employing around 1,000 world-class scientists, engineers and technicians, Philip Morris International now offers options to adult smokers who refuse to quit.

These new products that are being developed can change the lives of these individuals. The US Food and Drug Administration (FDA) has approved IQOS, Philip Morris International's innovative tobacco heating product, as a differentiated risk tobacco product, concluding that the available scientific evidence demonstrates that IQOS is expected to benefit the health of the population overall, taking into account both smokers and non-smokers.

The Beginning of a New Solution

"We had to transform our products and convey the story and the mission of what we are trying to do to the world," explained Massimo Andolina, an exercise that had not been always easy over the years. "Without a sense of purpose internally it would be impossible, but it is this sense that drives every single person working in the company nowadays. After all, at Philip Morris International, when something is difficult, it pushes us to go that extra mile. The existence of challenges can be the beginning of a new solution," he said.

Source: Protagon.gr The President of Europe of Philip Morris International - Massimo Andolina

Reducing Risk with Real Benefits

He spoke in detail about the importance of "harm reduction" achieved through differentiated risk tobacco products and the importance of a regulatory framework in this area. "We need to accelerate cooperation between stakeholders - we all have a role to play in this. It is important to look at the science, the technology, and the data to decide on what is convincing."

He also cited the example of Sweden, whose government was the first to adopt a positive attitude towards alternative tobacco products. As a result, Swedes now smoke far less than other Europeans, which has a significant and measurable impact on the health of the population. He also cited the example of Japan, one of the first countries to launch IQOS, thanks to which 1/3 of smokers have so far given up cigarettes.

Papastratos is a key piece of the puzzle

Mr. Andolina also referred to the important role Papastratos, a subsidiary of Philip Morris International, plays in Greece, with particular emphasis on what our country has to offer.

“We believe in the potential of the people we have here,” he said.

Besides, Papastratos is a “key piece of the puzzle” for Philip Morris International’s big shift. Already in 2017, a difficult time for the country, the company made an investment of 300 million euro, which transformed the Papastratos factory in Aspropyrgos into a unit for the exclusive production of heated tobacco rods for IQOS.

A major new investment of 200 million euro was also recently announced, with the addition of four new production lines at the Aspropyrgos plant, the creation of 300 new jobs and exports worth a total of 300 million euro, bringing the total investment since 2017 to date to 700 million euro.

The continuous investments in the company’s factory, in addition to increasing its production capacity, make the industry of the future a reality today, and support the extrovert orientation of the Greek economy. It is worth mentioning that 83% of Papastratos’ production is now exported to foreign markets.

A Future Without Cigarettes

How close might a cigarette-free future be? Massimo Andolina shared his own prediction: “It will happen in our lifetime. Greece could be one of the first cigarette-free countries in Europe, probably as early as 2030.”

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