



IQOS 2.4, IQOS 3.0, and HEETS MRTP Renewal

PMI U.S.

Tobacco Products Scientific Advisory Committee Meeting
October 7th, 2025

Introduction

Keagan Lenihan

Vice President and Chief External Affairs Officer, U.S.

Key Messages

- 1 ***IQOS Continues to Significantly Reduce HPHC Exposure***
- 2 ***Consumers Continue to Understand the Reduced Exposure Claim***
- 3 ***IQOS Users Switch From or Reduce Cigarette Use***
- 4 ***IQOS Use Among Youth is Very Low***

Authorized 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.

”

Authorized Products

IQOS 3.0

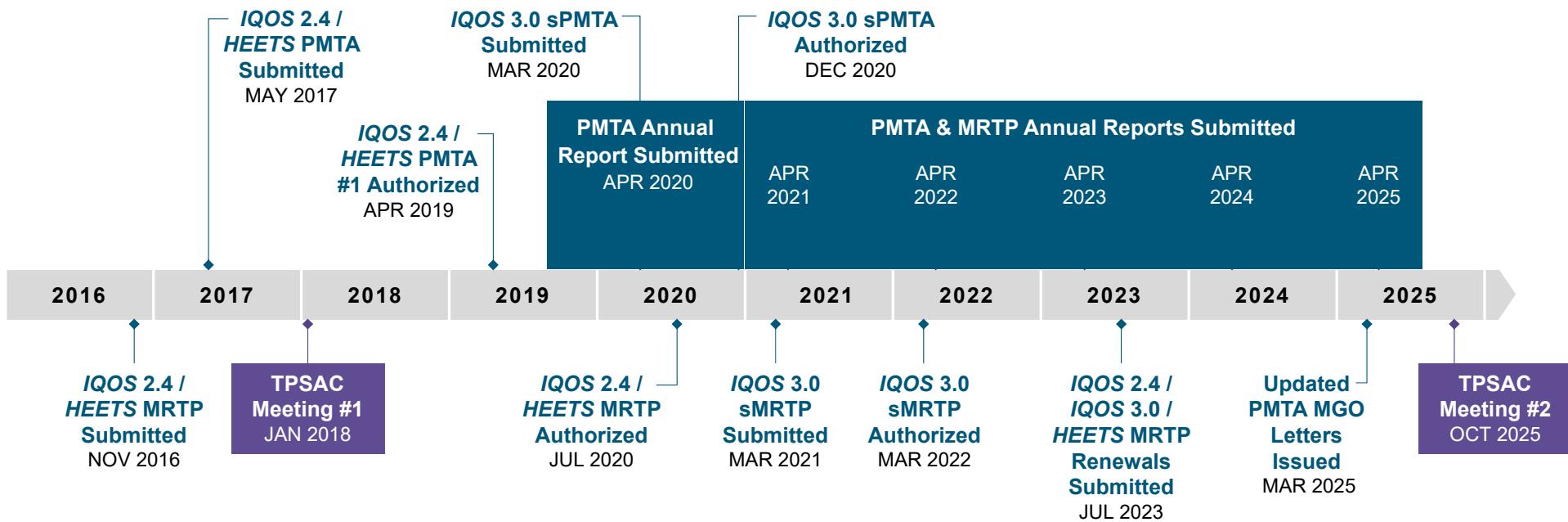


HEETS consumables



HTP Consumables were authorized under the names *Marlboro Heatsticks®*, *Marlboro Smooth Menthol Heatsticks®*, and *Marlboro Fresh Heatsticks®*. They were subsequently renamed as Amber *HEETS*, Blue *HEETS*, and Green *HEETS*, respectively. HTP Device was authorized under the name *IQOS 3.0 System Holder and Charger* and renamed as *IQOS Originals*. Given that product name changes do not render the tobacco products to be new tobacco products for which premarket authorization is required, PMP S.A. notified the FDA of this change on March 28, 2024, through the 30-day notification process.

Regulatory Timeline



U.S. Commercialization of *IQOS* Products



FDA Authorized *IQOS* with Reduced Exposure Claim

- *IQOS*, as actually used by consumers, has the potential to significantly reduce tobacco product users' exposure to harmful and potentially harmful constituents

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- Consumers understand the relative risk of *IQOS* compared to cigarettes, and the need to switch completely
- *IQOS*, when marketed with the reduced exposure claim, promotes complete switching and reduction in cigarette consumption
- Youth uptake of *IQOS* is low.

Postmarket Evidence Supports MRTP Renewal

Prior Evidence Led to PMTA Authorization



IQOS is APPH for both users and nonusers

Prior Evidence Led to MRTP Authorization



IQOS significantly reduces exposure to HPHCs

Postmarket Surveillance and Studies (PMSS)



All PMSS and reporting requirements have been met

Products Remain Modified Risk



PMSS results reinforce FDA's previous findings

**All postmarket evidence continues to demonstrate that
IQOS is appropriate to promote the public health
and is expected to benefit the health of the population as a whole**

Today's Speakers

Health Risks of IQOS Products

Patrick Picavet

Chief Medical Officer

Consumer Understanding, Perceptions, and Tobacco Use Behaviors

Pierpaolo Magnani

Global Head of Regulatory Insights

Responsible Marketing and Controls

JB Simko

Vice President and Chief U.S. Underage Prevention Officer

Conclusion

Keagan Lenihan

Vice President and Chief External Affairs Officer, US

Health Risks of *IQOS* Products

Patrick Picavet

Chief Medical Officer

Assessing Health Risks of IQOS Products

1

**Reduced
HPHCs**

Non-Targeted
Differential Screening
(NTDS)

2

**Reduced Estimated
Carcinogenic Risk**

Cumulative Excess
Lifetime Cancer Risk
(ELCRc)

3

**Reduced
Exposure**

Biomarkers of
Exposure
(BOEs)

Biomarkers of
Potential Harm
(BOPHs)

FDA's Prior Conclusions

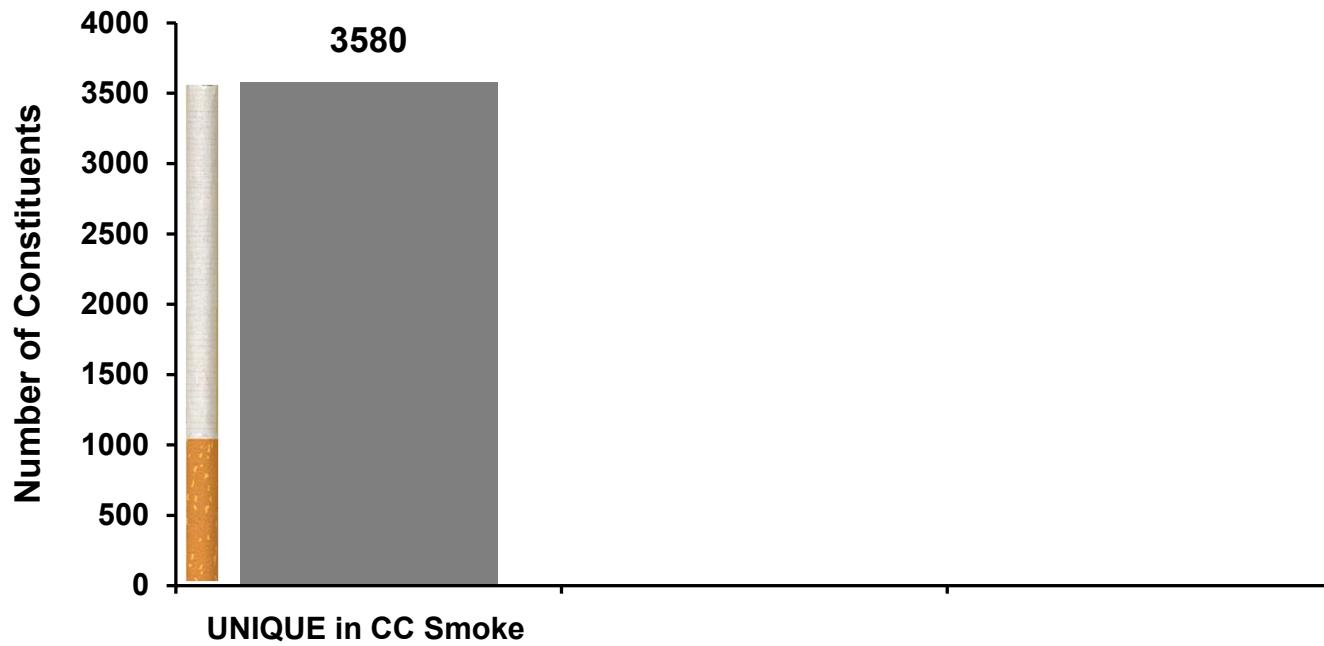
HPHCs



“ When assessing the overall yield of chemicals...the yields of potential carcinogens, respiratory toxicants, and reproductive/developmental toxicants were ***considerably lower in Heatstick aerosols*** compared with combusted cigarette smoke. ”

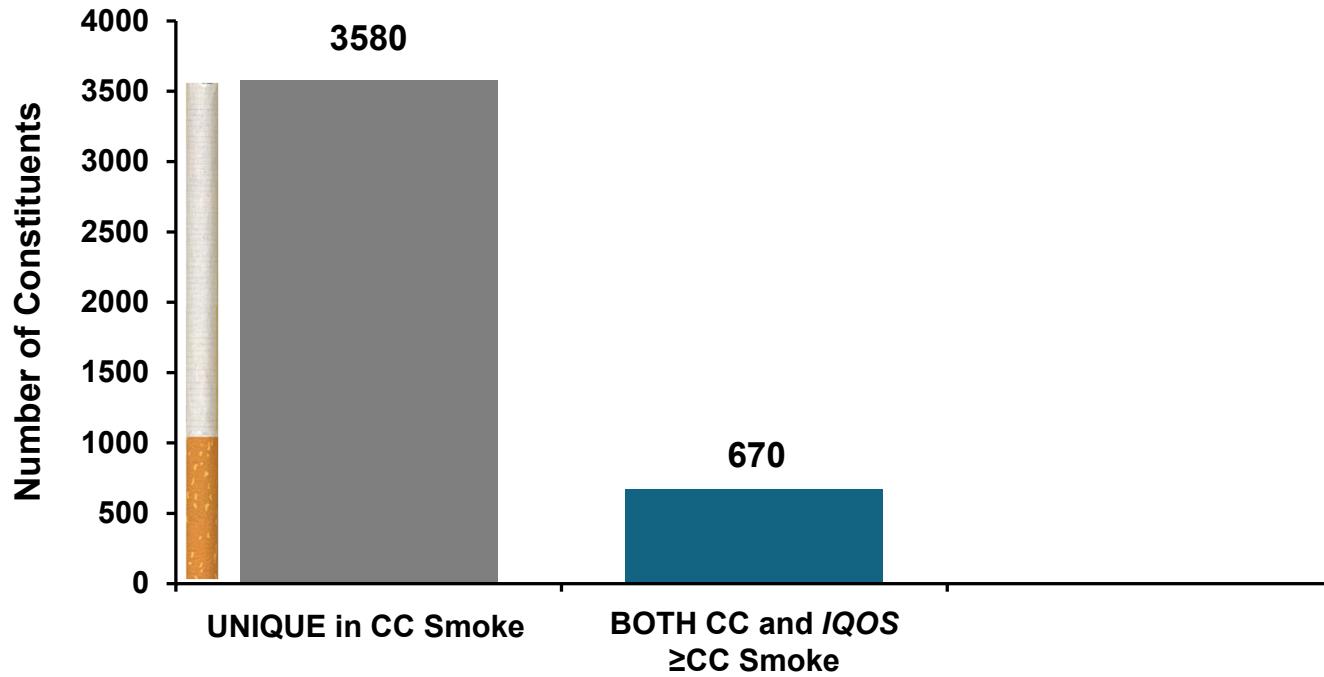
– *FDA 2020 MRTP TPL Review*
(emphasis added)

NTDS: Comparison of Cigarette Smoke and IQOS Aerosol



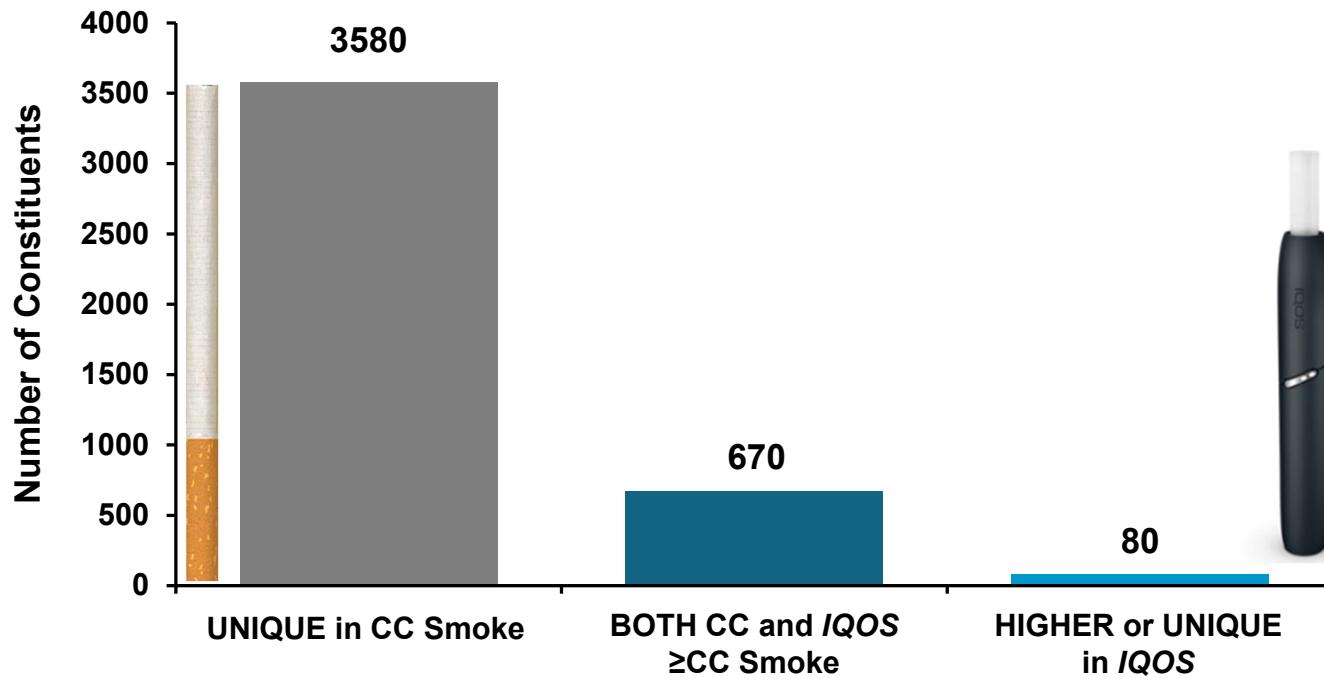
CC = Combusted Cigarette
Constituents were present in >100ng/stick
Source: PMSS- Computational Toxicology Report

NTDS: Comparison of Cigarette Smoke and IQOS Aerosol

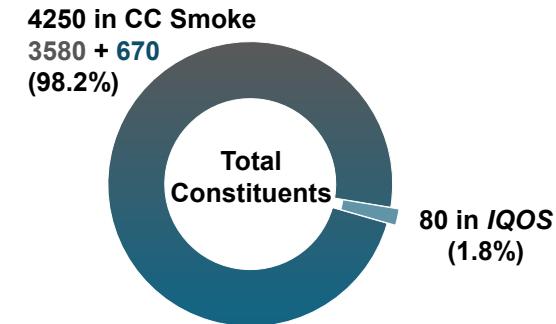


CC = Combusted Cigarette
Constituents were present in >100ng/stick
Source: PMSS- Computational Toxicology Report

NTDS: Comparison of Cigarette Smoke and IQOS Aerosol



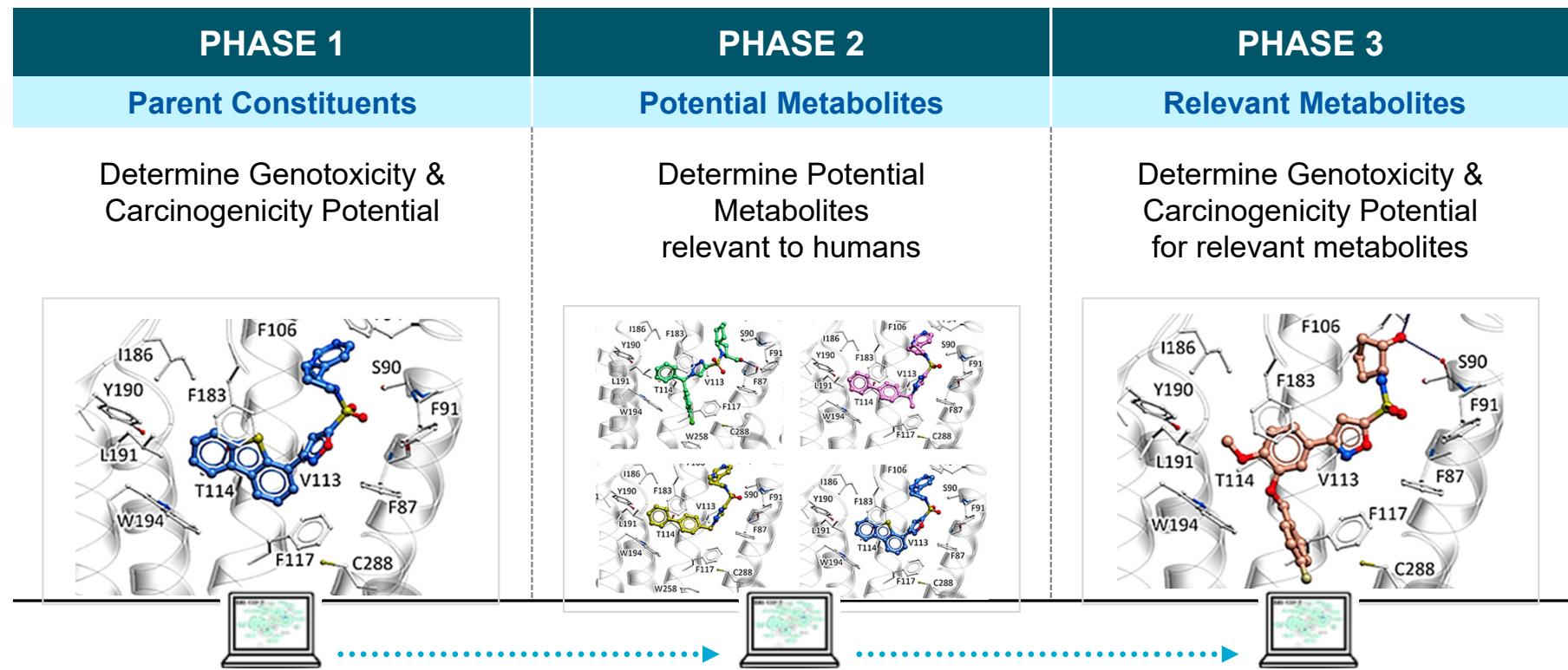
CC Compared to IQOS



SMALL NUMBER AND
LOW LEVELS OF
IQOS CONSTITUENTS
OUTWEIGH CONCERNS

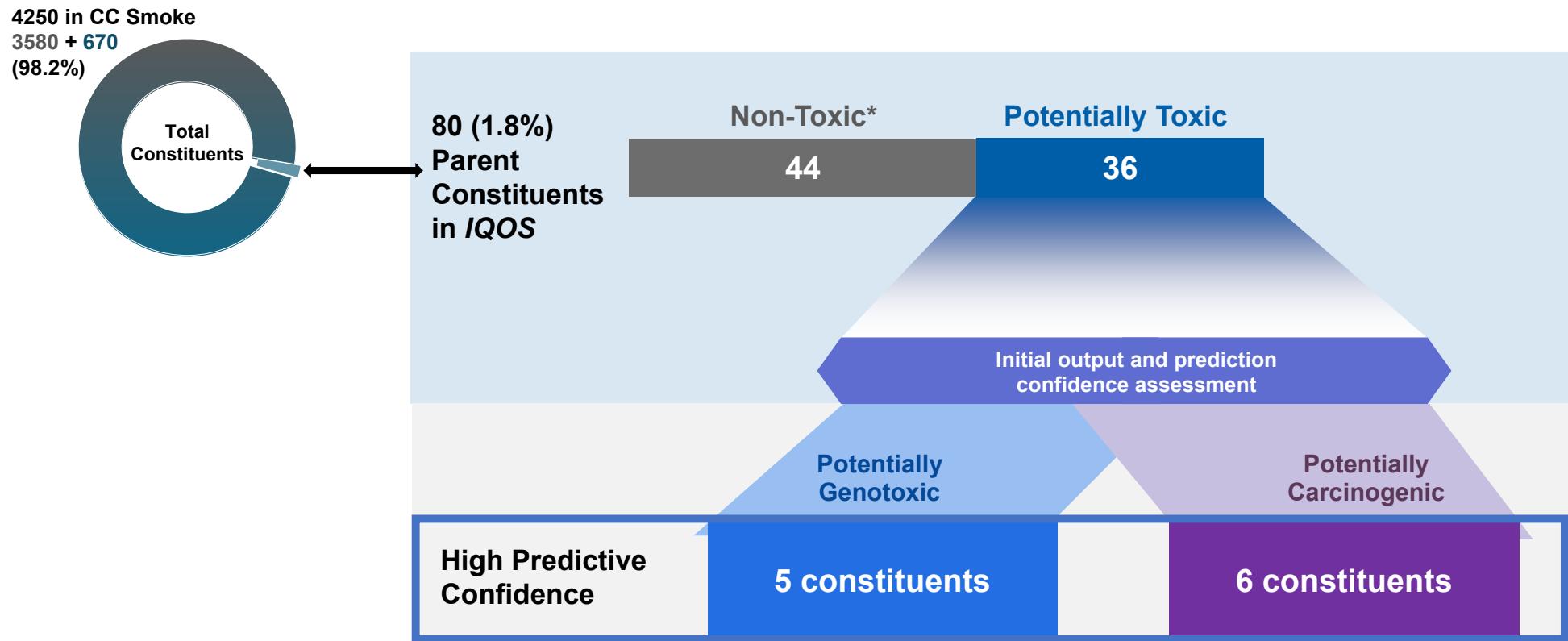
CC = Combusted Cigarette
Constituents were present in $>100\text{ng/stick}$
Source: PMSS- Computational Toxicology Report

Study Design: Computational Toxicology Assessment



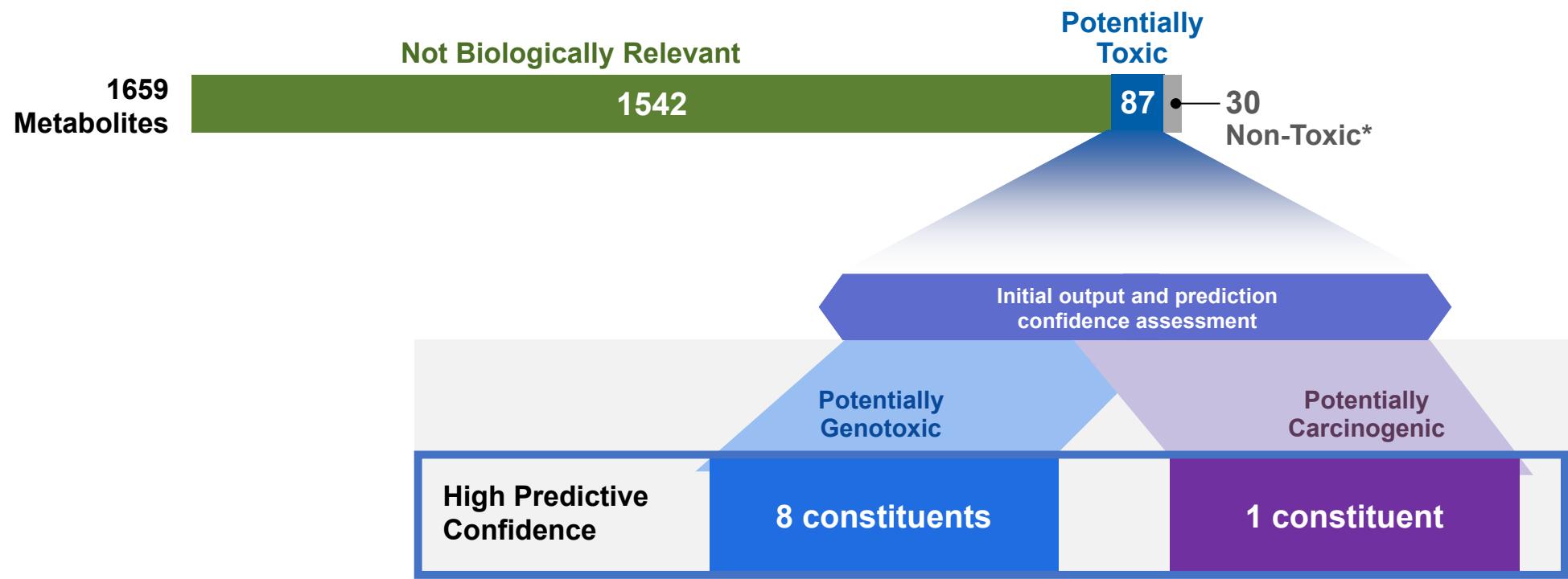
Source: PMSS- Computational Toxicology Report

Parent Constituents: Genotoxic and Carcinogenic Potential



*Regarding assessments of genotoxicity and carcinogenicity
Source: PMSS- Computational Toxicology Report

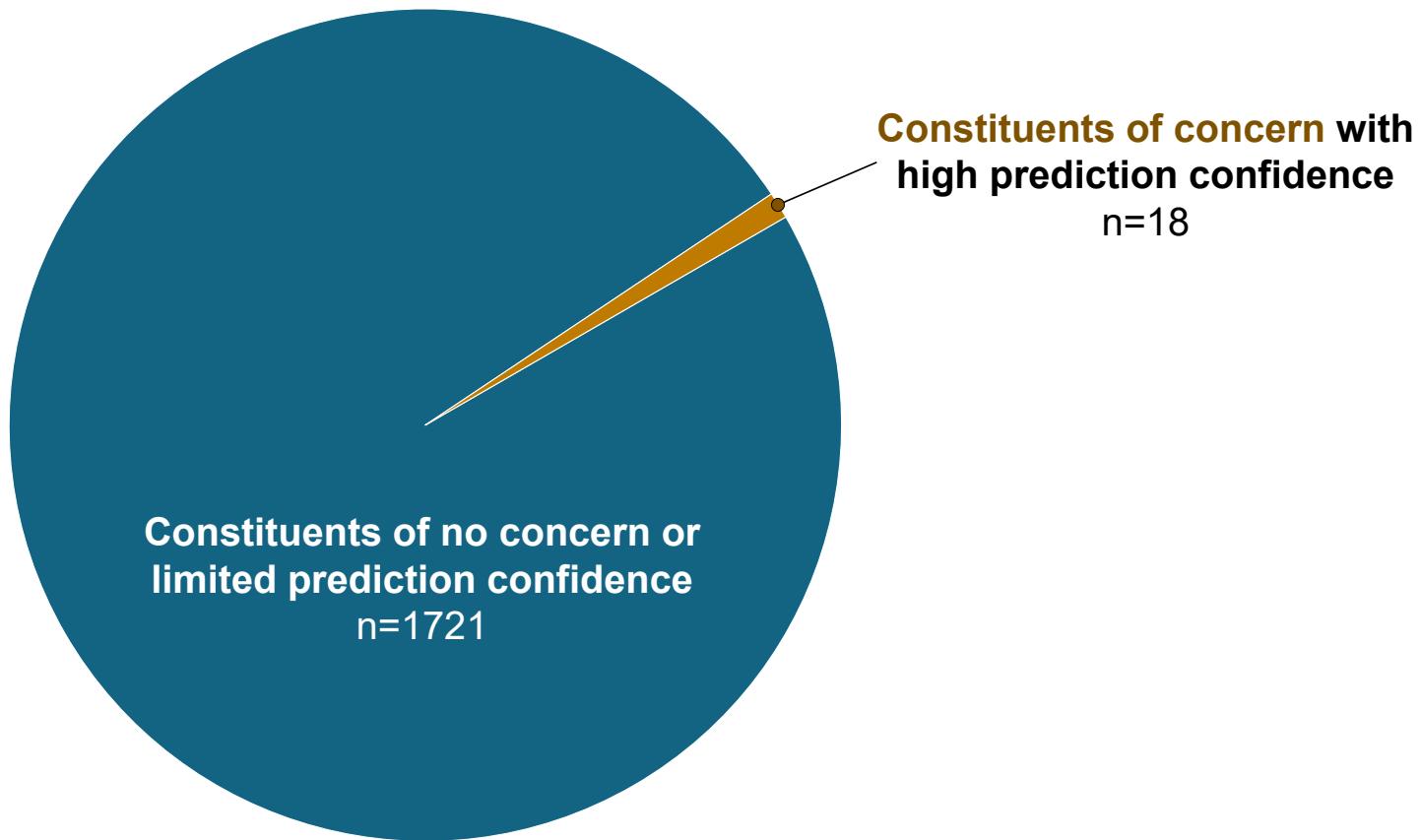
Parent Constituents' Metabolites: Genotoxic and Carcinogenic Potential



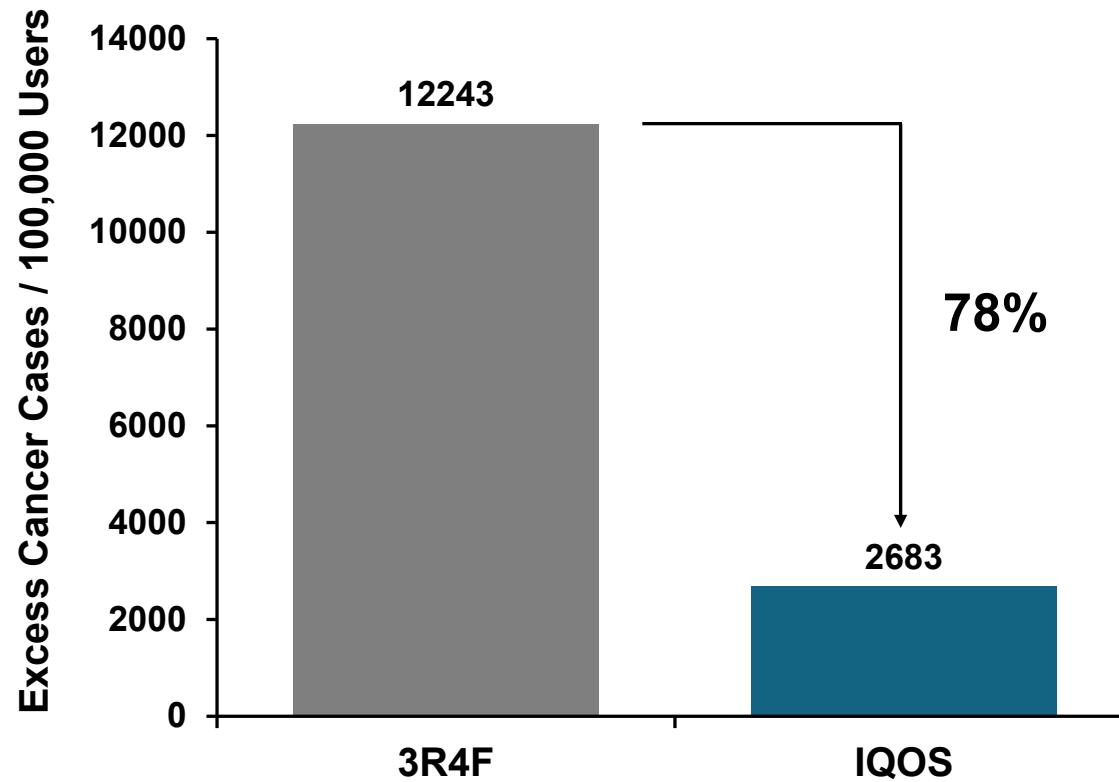
*Regarding assessments of genotoxicity and carcinogenicity
Source: PMSS- Computational Toxicology Report

CC-22

Majority of Parent Constituents and Metabolites in IQOS Pose No Toxicological Concern



Estimation of ELCR_c for IQOS Aerosols vs. 3R4F Smoke



Source: Response to FDA A/I Request letter issued on November 22nd, 2024

FDA's Prior Conclusions

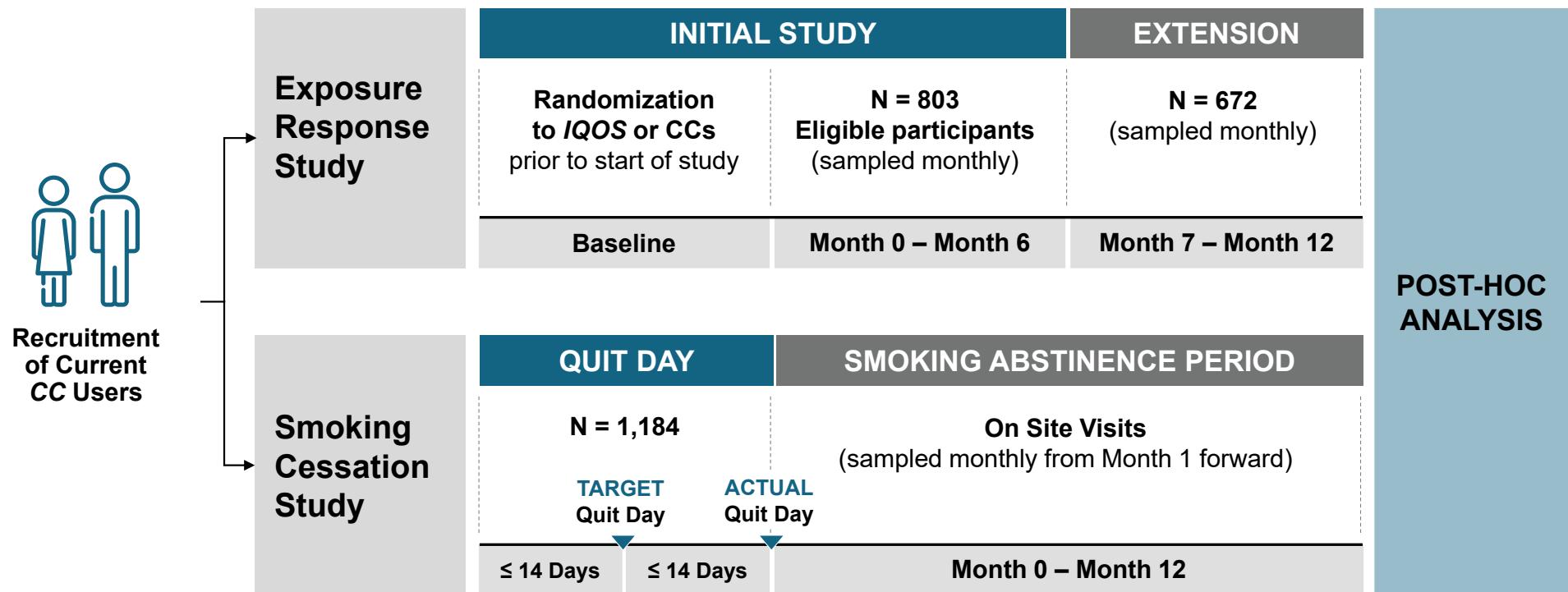
BOEs



“ Findings from the clinical studies suggest a ***significant reduction in BOEs to 15 HPHCs when smokers switch completely to IQOS.*** The reduced BOEs reflect a range of chemical and toxicity classes. ”

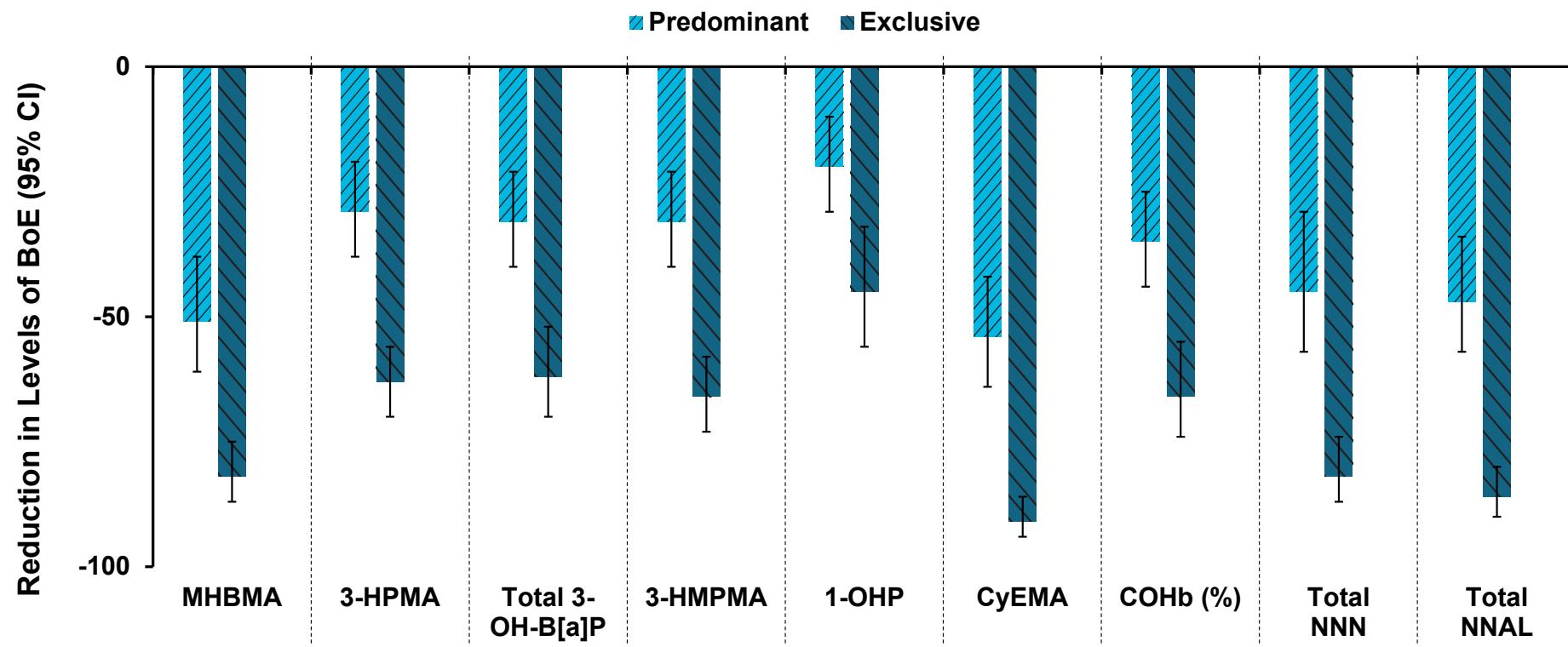
– *FDA 2020 MRTP TPL Review*
(emphasis added)

Study Design: Additional Studies Assessing BOEs



Source: Exposure Response Study – ZRHR-ERS-09-US; Extension of Study – ZRHR-ERS-09-EXT-US; Smoking Cessation Study – SA-SCR-01; Post-hoc analysis – P1-ERS-EXT-SCR-PH-SHP

Changes in BOEs with IQOS Use vs Smoking at 6 Months

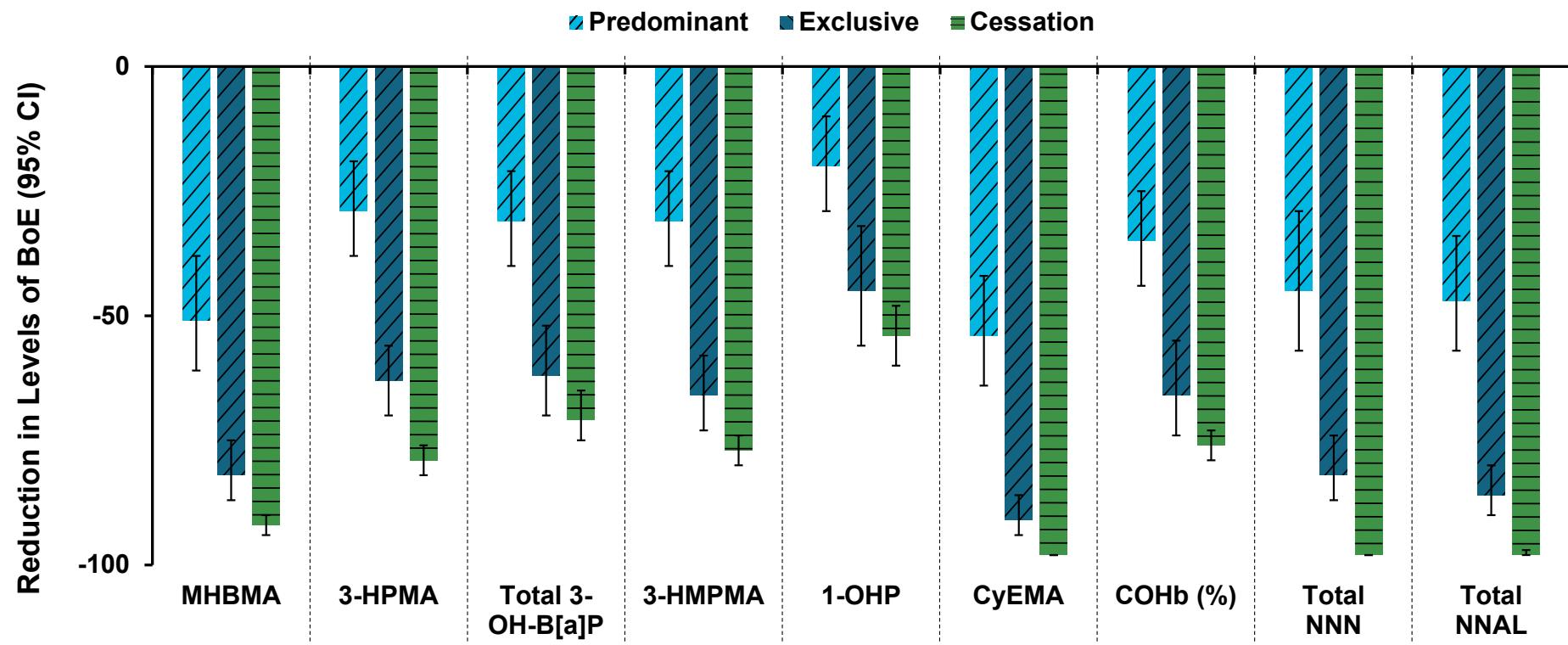


All results shown were statistically significant

MHBMA: Monohydroxy-3-butenyl mercapturic acid; 3-HPMA: 3-Hydroxypropylmercapturic acid; 3-OH-B[a]P: 3-Hydroxybenzo[a]pyrene; 3-HMPMA: 3-Hydroxy-1-ethylpropylmercapturic acid; 1-OHP: 1-Hydroxypyrene; NNN: N-Nitrosornicotine; 2CyEMA: 2-Cyanoethylmercapturic acid

Source: Post-Hoc Analysis – P1-ERS-EXT-SCR-PH-SHP

Changes in BOEs with IQOS Use and Cessation vs Smoking at 6 Months

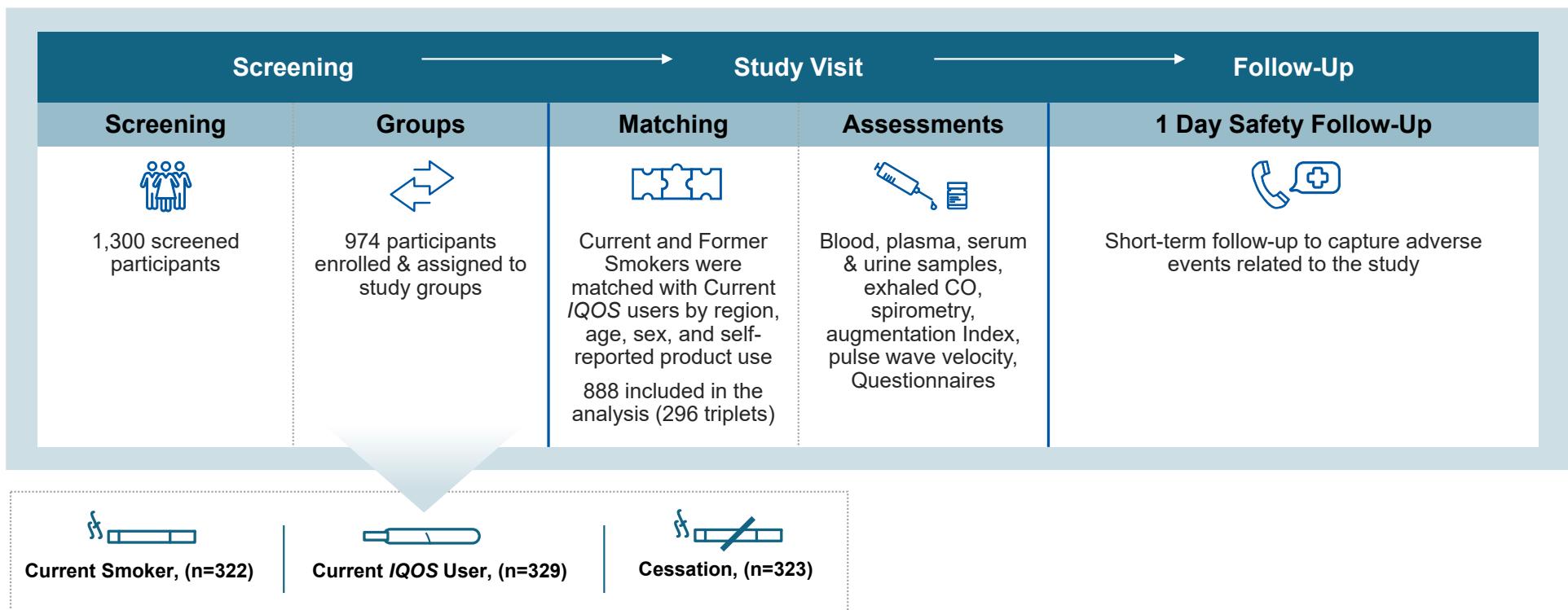


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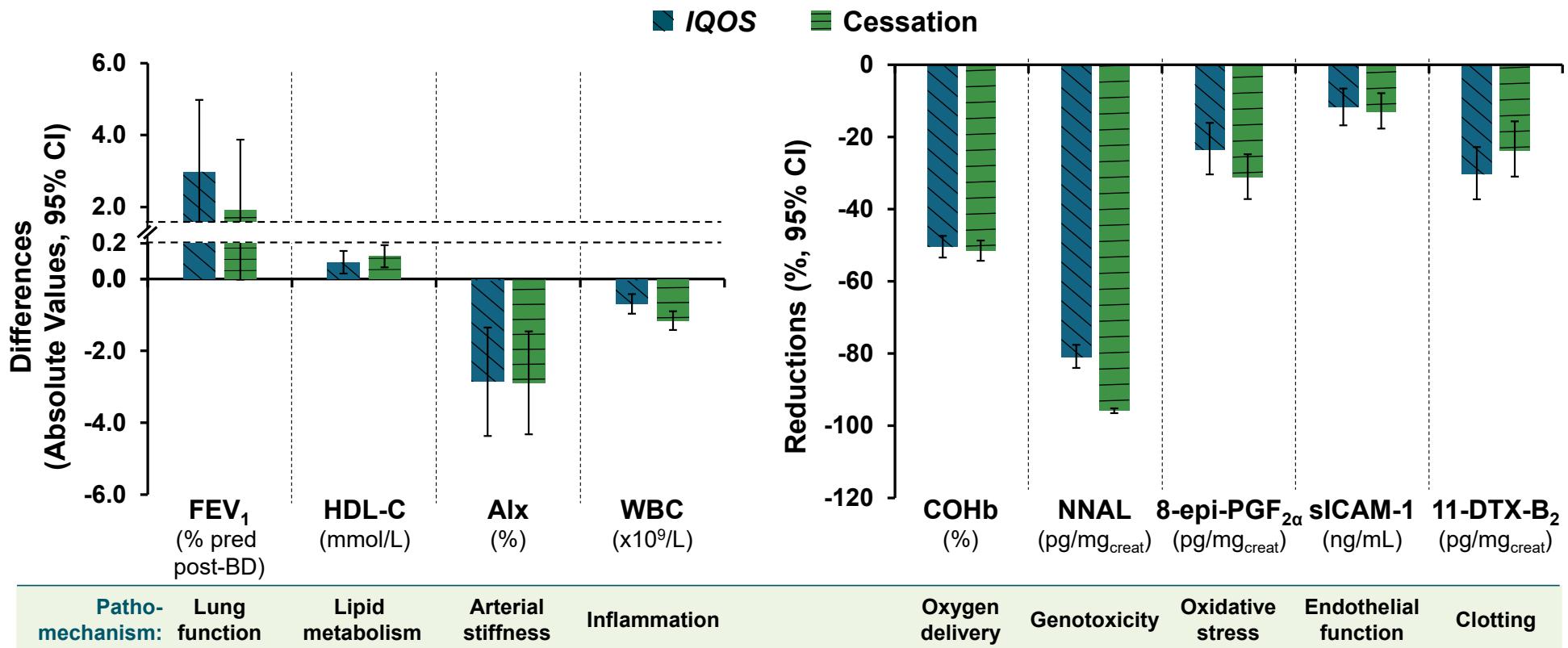
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Source: Post-Hoc Analysis – P1-ERS-EXT-SCR-PH-SHP

Study Design: Risk Marker Cross-Sectional Study



Changes in BOPHS with IQOS Use and Cessation vs Smoking



Alx: augmentation index; COHb: carboxyhemoglobin; 11-DTX-B2: 11-dehydrothromboxane B2; 8-epi-PGF2α: 8-epi-prostaglandin-F2α; FEV₁ %pred post-BD: forced expiratory volume in 1 second %predicted, post-bronchodilator; HDL-C: high-density lipoprotein cholesterol; sICAM-1: soluble intercellular adhesion molecule-1; Total NNAL: total 4-(methylnitrosamo)-1-(3-pyridyl)-1-butanol; WBC: white blood cell count

Source: Risk Marker Cross-Sectional Study – P1-RMC-03-INT

FDA's Prior Conclusions

Reduction in Tobacco-Related Disease



“

The totality of evidence presented suggests that a ***measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely***... This determination predominantly stems from the substantial reduction in HPHCs relative to combusted cigarette smoke.”

”

– *FDA 2020 MRTP TPL Review*
(emphasis added)

Consumer Understanding, Perceptions, and Tobacco Use Behaviors

Pierpaolo Magnani

Global Head of Regulatory Insights

Consumer Understanding, Perceptions, and Tobacco Use Behaviors of *IQOS* Products

1

**Correct claim
understanding**

Postmarket Adult
Consumer Study
(PACS)

2

**Positive impact
on use behavior**

Postmarket Adult
Consumer Study
(PACS)

IQOS Owners Panel

3

**Very low uptake
in youth**

Underage Tobacco
Use Survey
(UTUS)

FDA's Prior Conclusions

Consumer Understanding and Perceptions



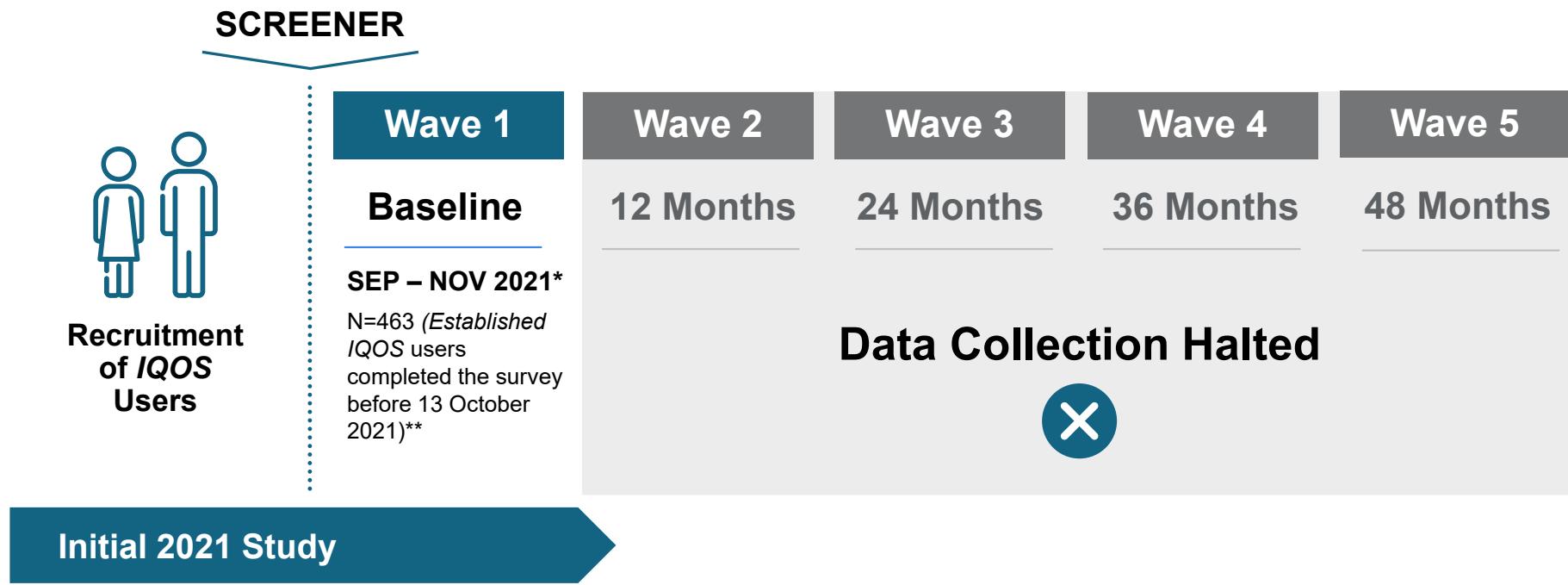
“

Actual consumer perception testing supports that *consumer understanding is in line with the relative risks of the product* that are reasonably likely. Importantly, consumers did not interpret the proposed claim to mean that the product causes no risk.

”

– *FDA 2020 MRTP TPL Review*
(emphasis added)

Study Design: IQOS Cross-Sectional PACS



*On October 13th, 2021, an information letter was sent to study participants stating that IQOS would be unavailable for sale in the U.S. as of November 28th, 2021.

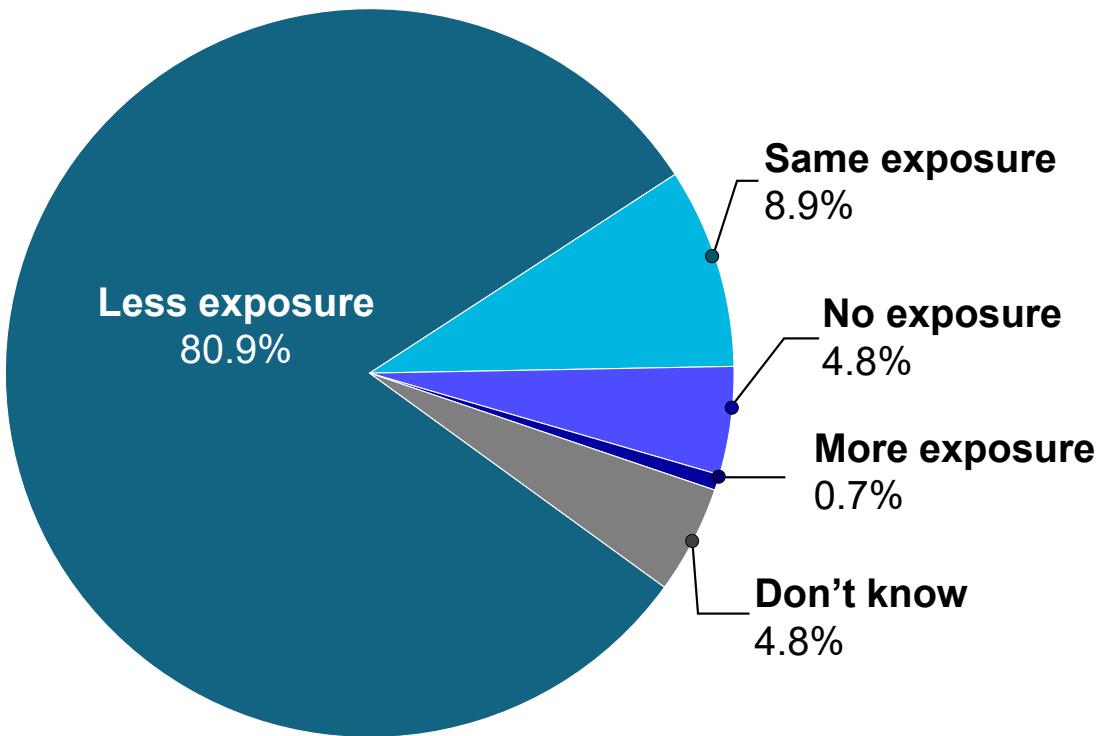
** Established IQOS users defined as reporting having ever used IQOS and having used 100 or more HEETS in their lifetime.

Source: Cross-Sectional PACS

Consumers Understand Reduced Exposure to HPHCs When Using *IQOS* Instead of Cigarettes

Perception about HPHC exposure when switching completely from cigarettes to *IQOS*

Current *IQOS* Users
(N=439)



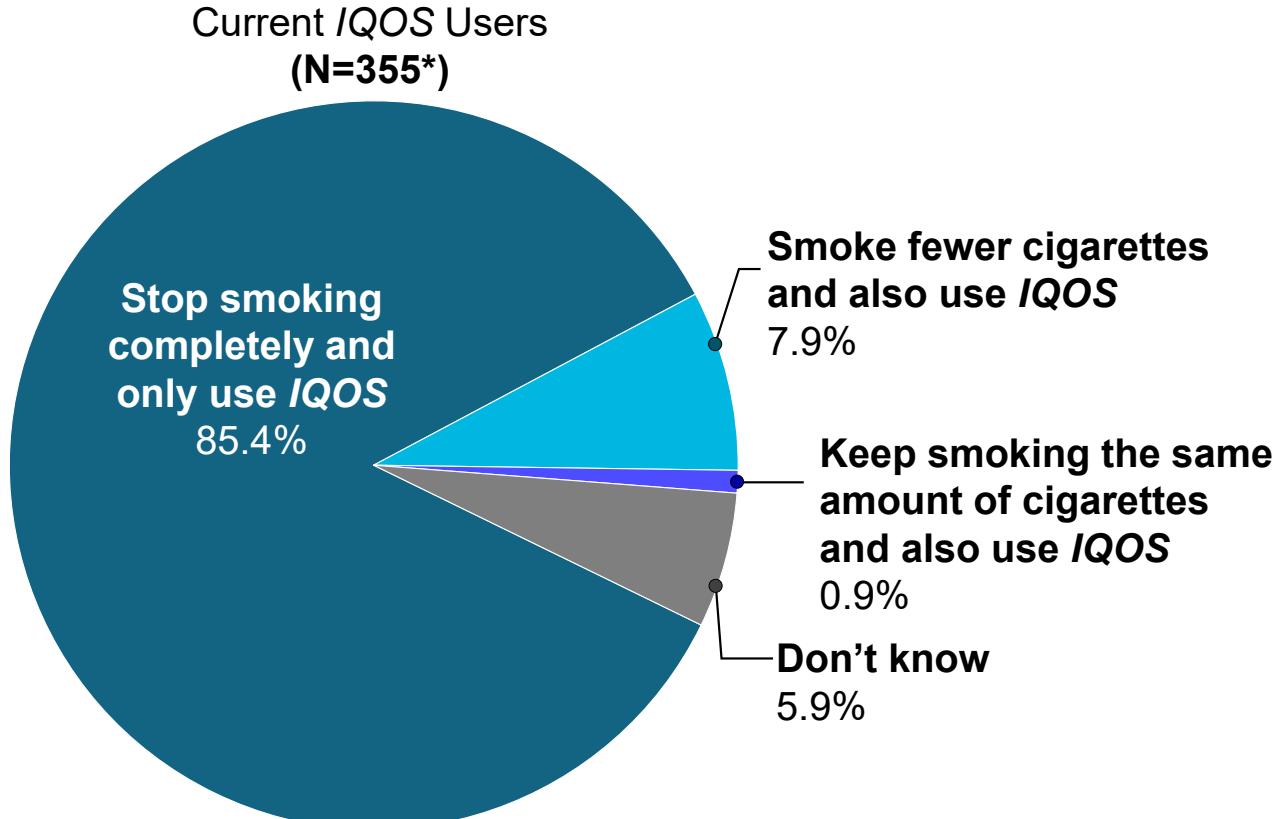
Base: Current established *IQOS* users defined as reporting using *IQOS* "Every day" or "Some days" at time of survey and having used 100 or more *HEETS* in their lifetime

Note: The sum of the percentages may not equal 100% due to rounding

Source: Cross-Sectional PACS

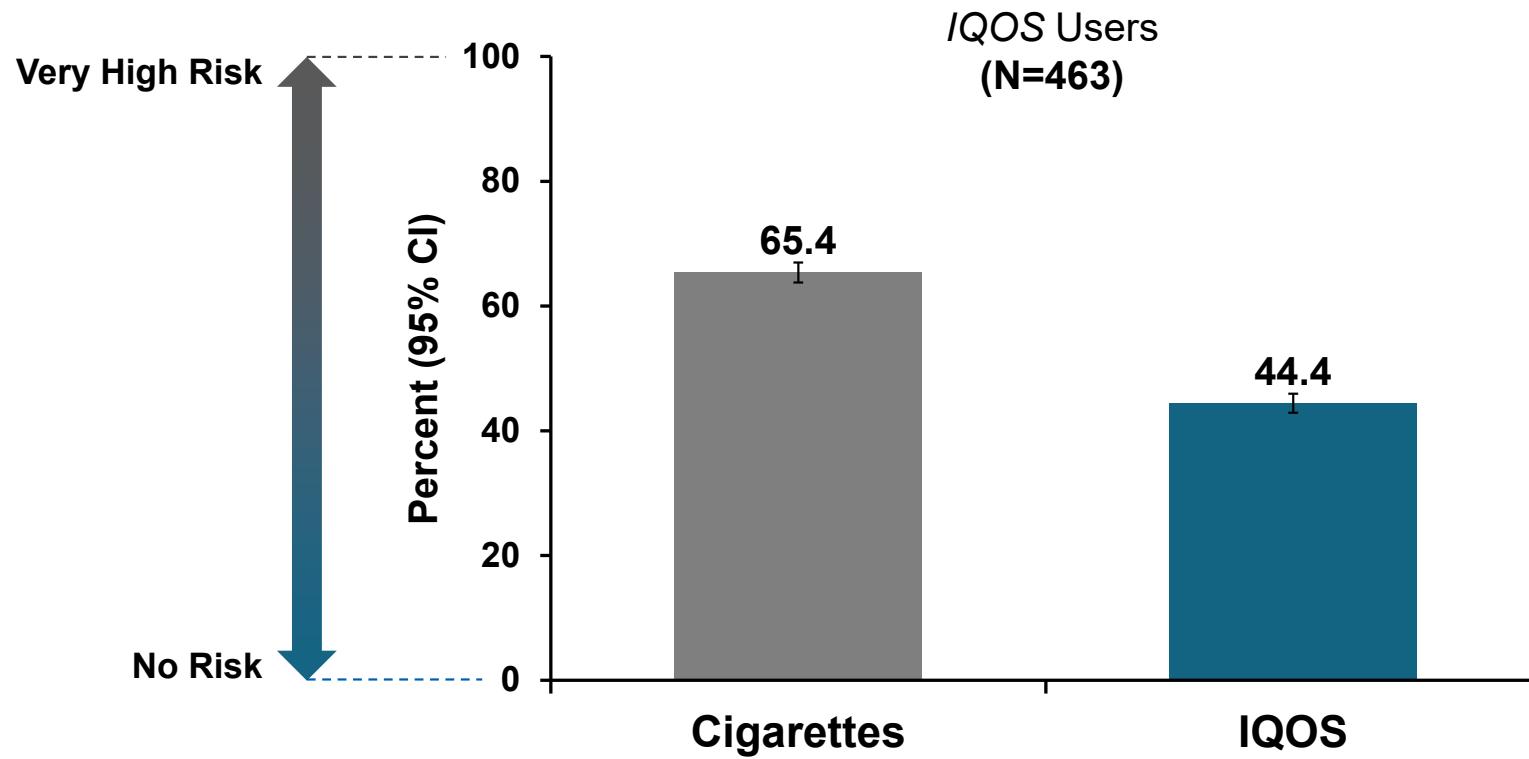
Consumers Understand Need to Completely Switch to Reduce Exposure to HPHCs

Understanding of what smokers must do to reduce their exposure to HPHCs



*This question was asked of only those respondents who correctly identified that using IQOS instead of cigarettes reduces their exposure to harmful or potentially harmful chemicals.
Base: Current established IQOS users defined as reporting using IQOS "Every day" or "Some days" at time of survey and having used 100 or more HEETS in their lifetime.
Note: The sum of the percentages may not equal 100% due to rounding
Source: Cross-Sectional PACS

Consumers Perceived the Health Risks of IQOS as being lower than Cigarettes but Not Risk Free



Error bars: 95% confidence interval

Base: Established IQOS users defined as reporting having ever used IQOS and having used 100 or more HEETS in their lifetime.

Participants were asked to rate the general perceived risk of getting 18 different diseases or adverse health conditions separately for smoking cigarettes or for using IQOS™ on a 5-point Likert-like scale (ranging from 0 [no risk] to 4 [very high risk]) using PMP S.A.'s psychometrically validated ABOUT—Perceived Risk, General version, Health Risk Instrument (18-item). Based on the 18 rated items, an overall score ranging from 0 [no risk] to 100 [very high risk] was derived from the total raw score by Rasch model analysis.

Source: Cross-Sectional PACS

FDA's Prior Conclusions

Tobacco Use Behaviors



“

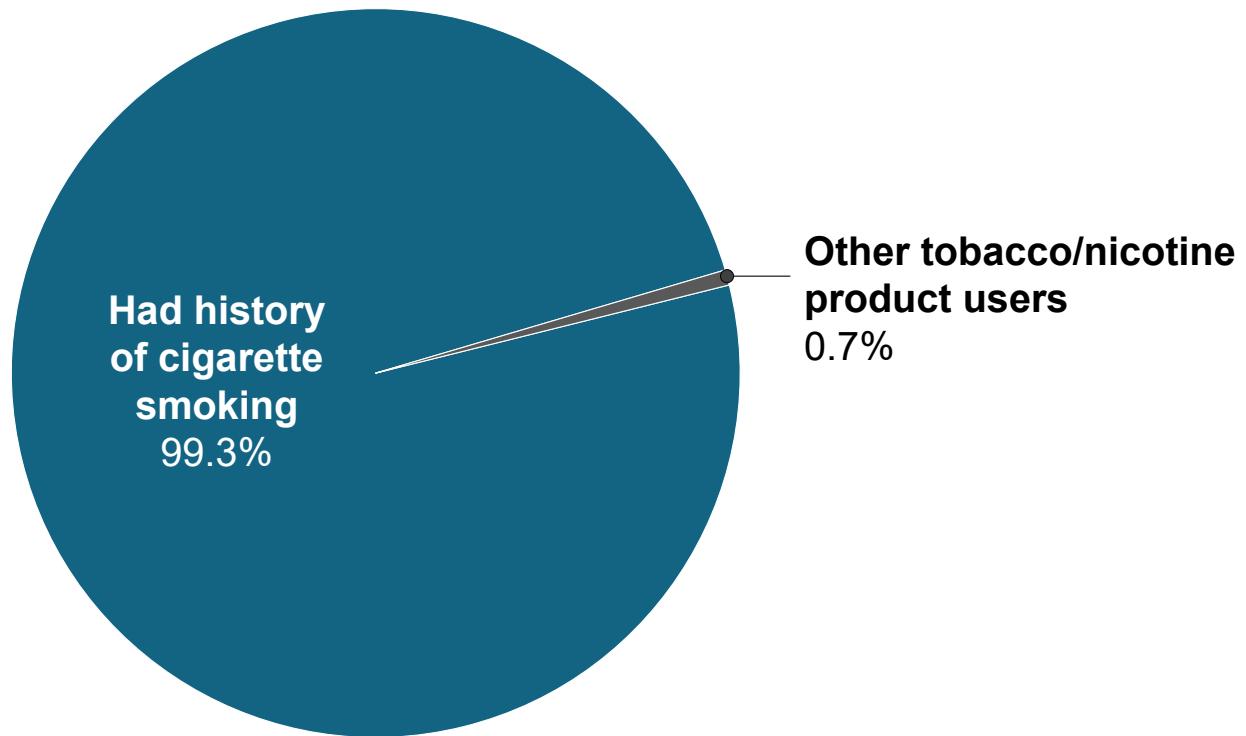
Marketing IQOS with a reduced exposure claim could ***appeal to current smokers who are most likely to benefit from their use***, and this supports a likely benefit to population health.

”

*FDA 2020 MRTP & 2022 sMRTP TPL Review
(emphasis added)*

All IQOS Users Have a Tobacco Use History

Cigarette Smoking or Other TNPs Use Status among Current IQOS Users
(N=439)



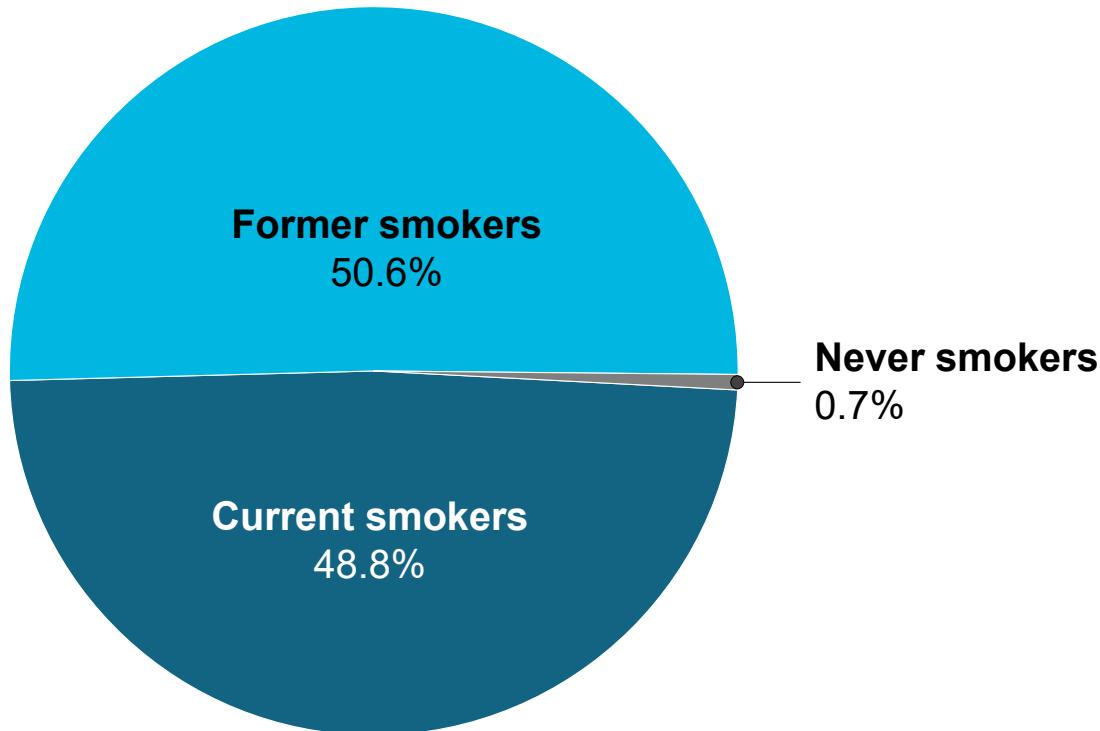
Base: Current established IQOS users defined as reporting using IQOS "Every day" or "Some days" at time of survey and having used 100 or more HEETS in their lifetime.

TNP = Tobacco or Nicotine Products

Source: Cross-Sectional PACS

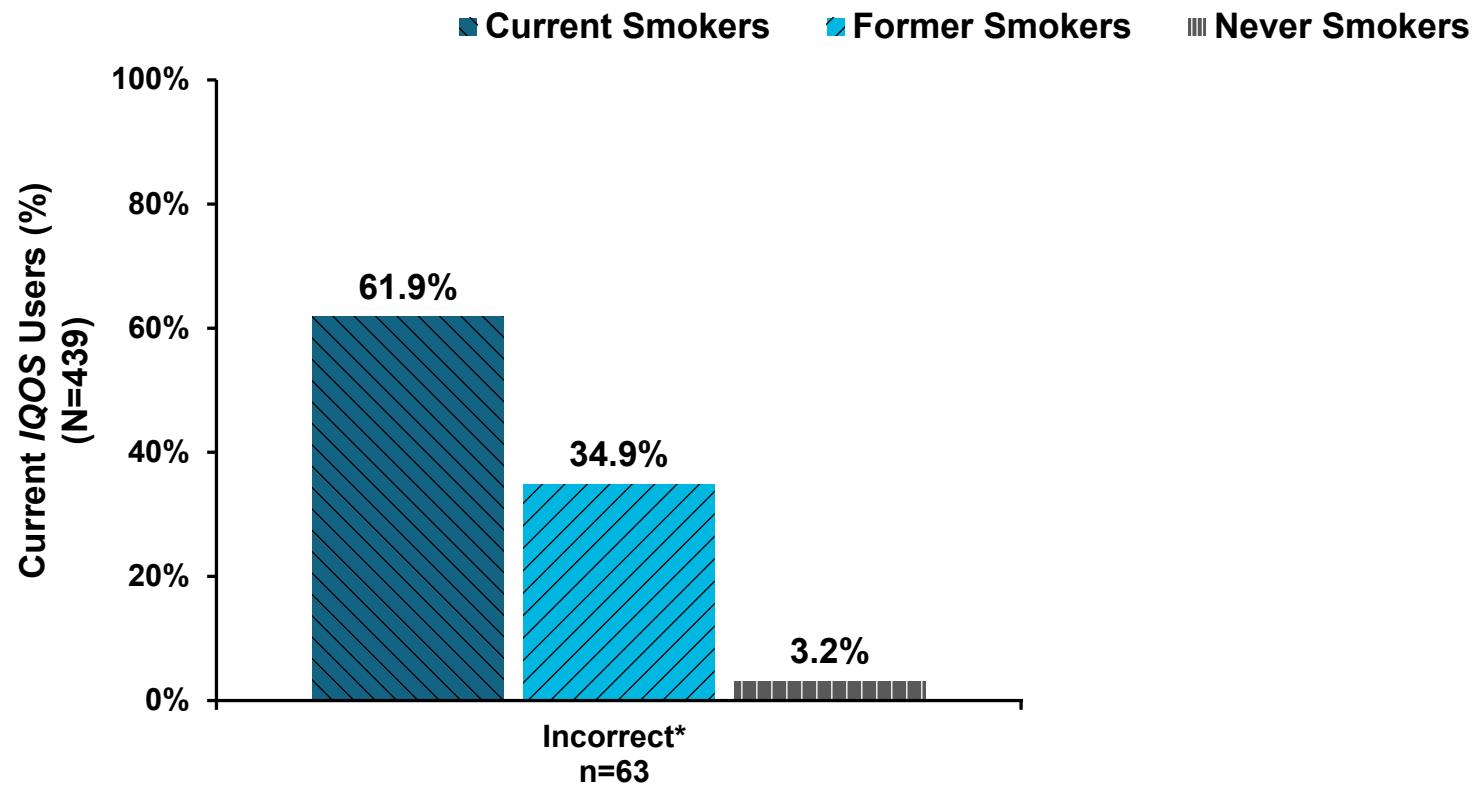
IQOS Users are Switching from Cigarette Smoking

**Cigarette Smoking Status Among Current IQOS Users
(N=439)**



Base: Current established IQOS users defined as reporting using IQOS "Every day" or "Some days" at time of survey and having used 100 or more HEETS in their lifetime.
Current smokers defined as reporting smoking cigarettes "Every day" or "Some days" at the time of survey. Former smokers defined as reporting having ever smoked but smoking cigarettes "Not at all" at the time of survey.
Never smokers defined as reporting having ever smoked
Note: The sum of the percentages may not equal 100% due to rounding
Source: Cross-Sectional PACS

Cigarette Smoking Status According to Understanding of Reduced Exposure to HPHCs

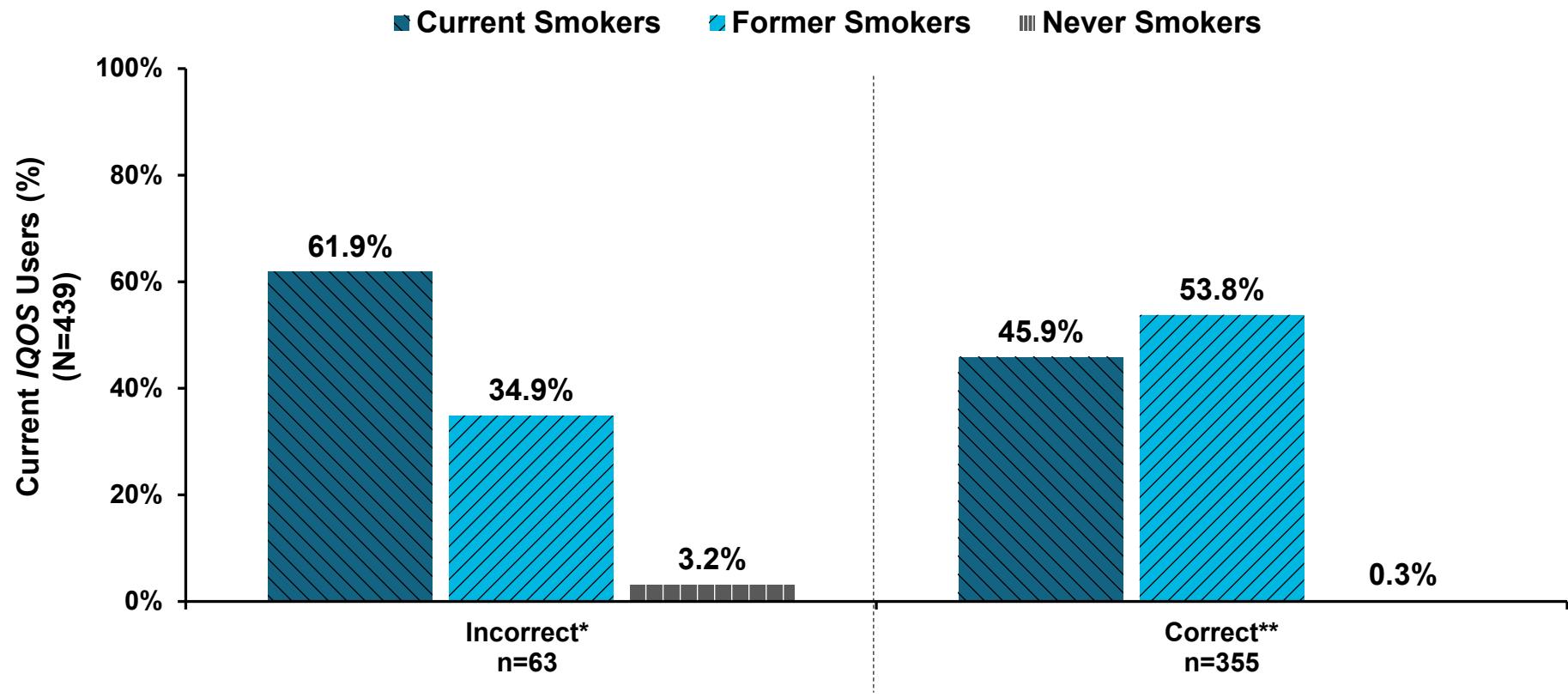


* Incorrect responses include "have more exposure to HPHCs", "have the same exposure to HPHCs", and "have no exposure to HPHCs". This analysis does not include "don't know" (n=21).

**Correct response: "have less exposure to HPHCs".

Source: Cross-Sectional PACS

Cigarette Smoking Status According to Understanding of Reduced Exposure to HPHCs



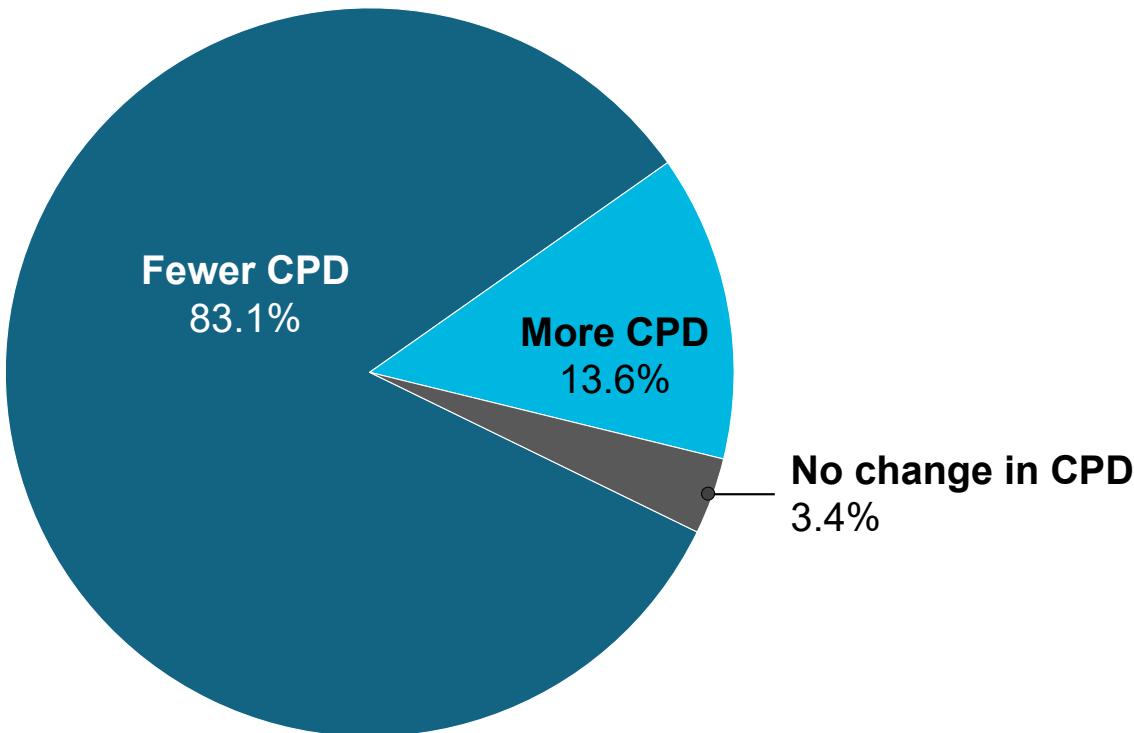
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**Correct response: "have less exposure to HPHCs".

Source: Cross-Sectional PACS

IQOS Users are Reducing their Cigarette Consumption

Change in Cigarette Consumption* Among Current Smokers
(N=207)**



CPD = Cigarettes Per Day

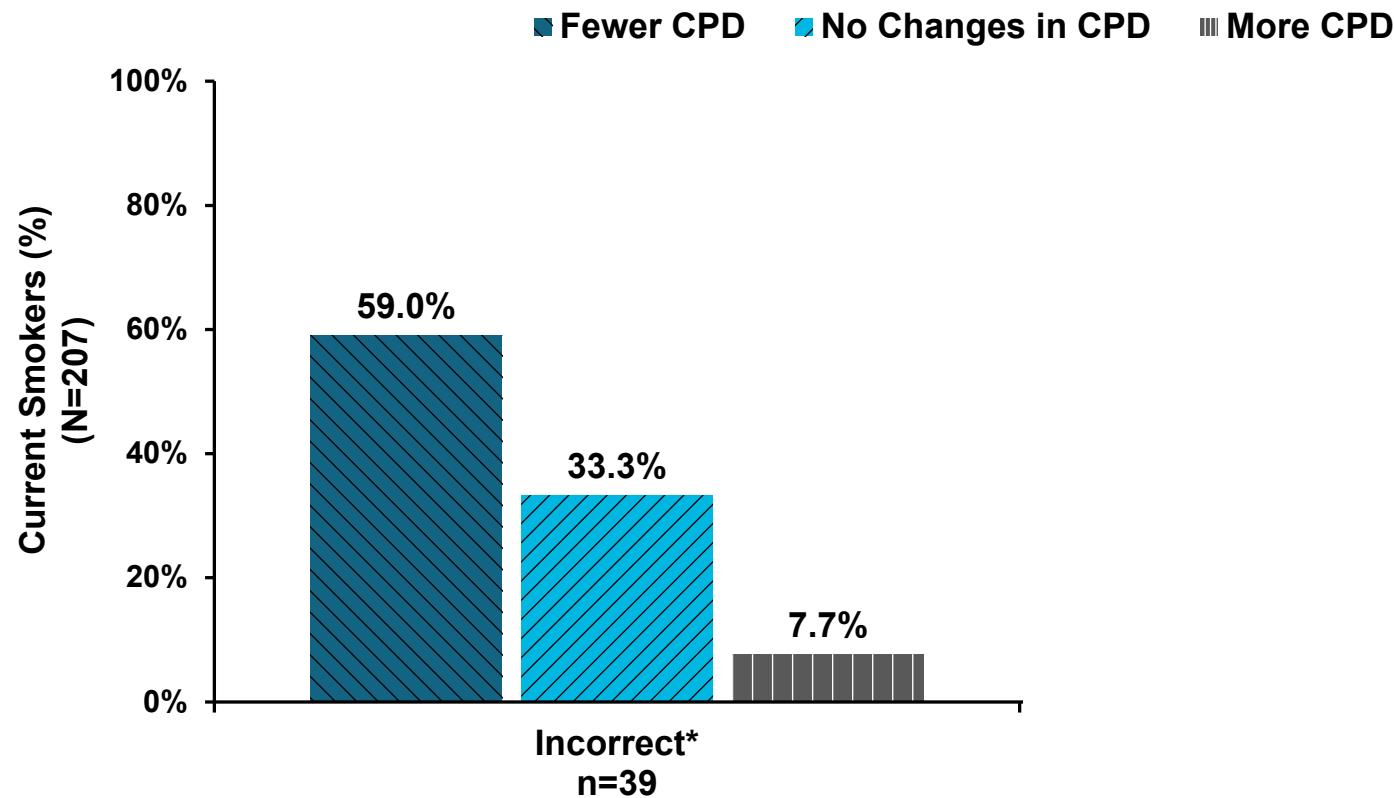
*Compared to the 30 days before the first trial of IQOS.

** Current smokers defined as reporting smoking cigarettes "Every day" or "Some days" at the time of survey and had smoked cigarettes 30 days before the survey.

Note: The sum of the percentages may not equal 100% due to rounding

Source: Cross-Sectional PACS

Changes in Cigarette Consumption According to Understanding of Reduced Exposure to HPHCs

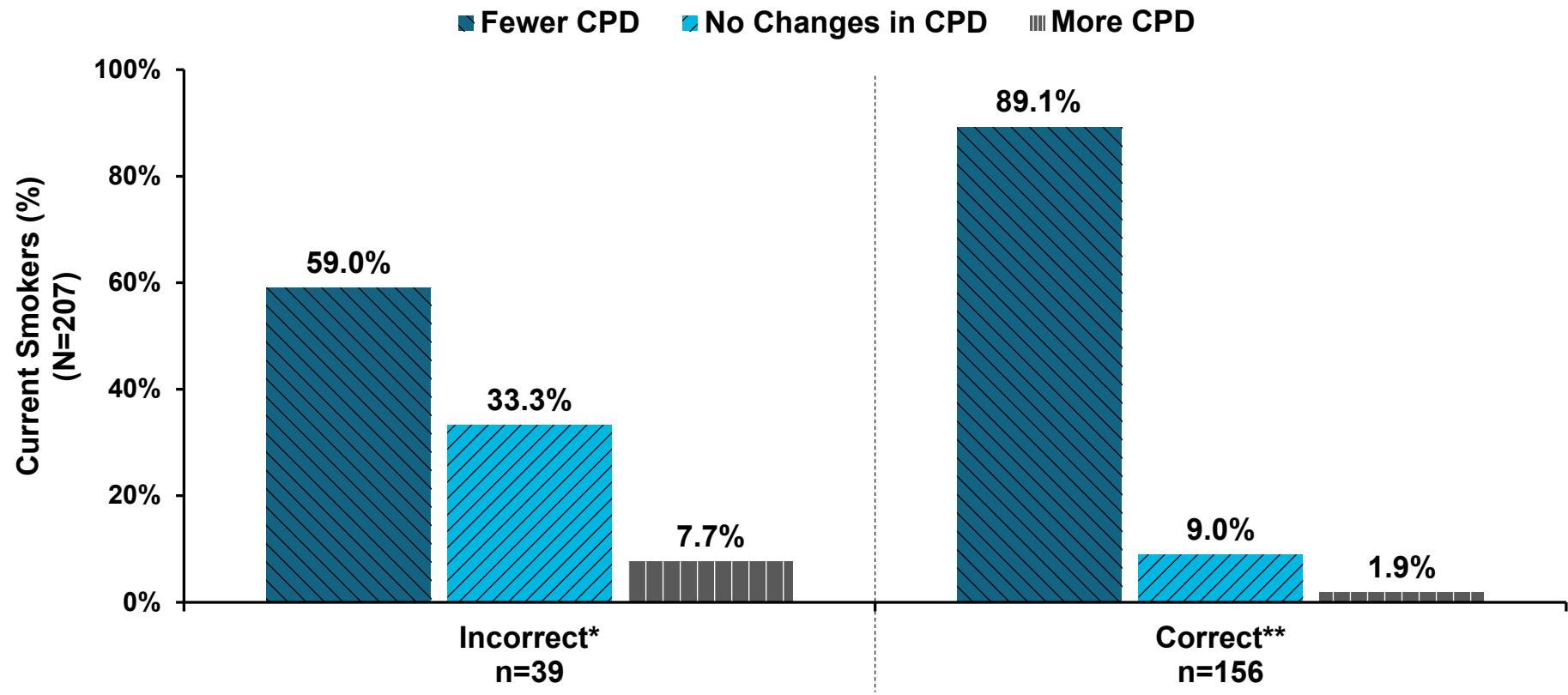


*Incorrect responses include "have more exposure to HPHCs", "have the same exposure to HPHCs", and "have no exposure to HPHCs". This analysis does not include "don't know" (n=12).

**Correct response: "have less exposure to HPHCs".

Source: Cross-Sectional PACS

Changes in Cigarette Consumption According to Understanding of Reduced Exposure to HPHCs

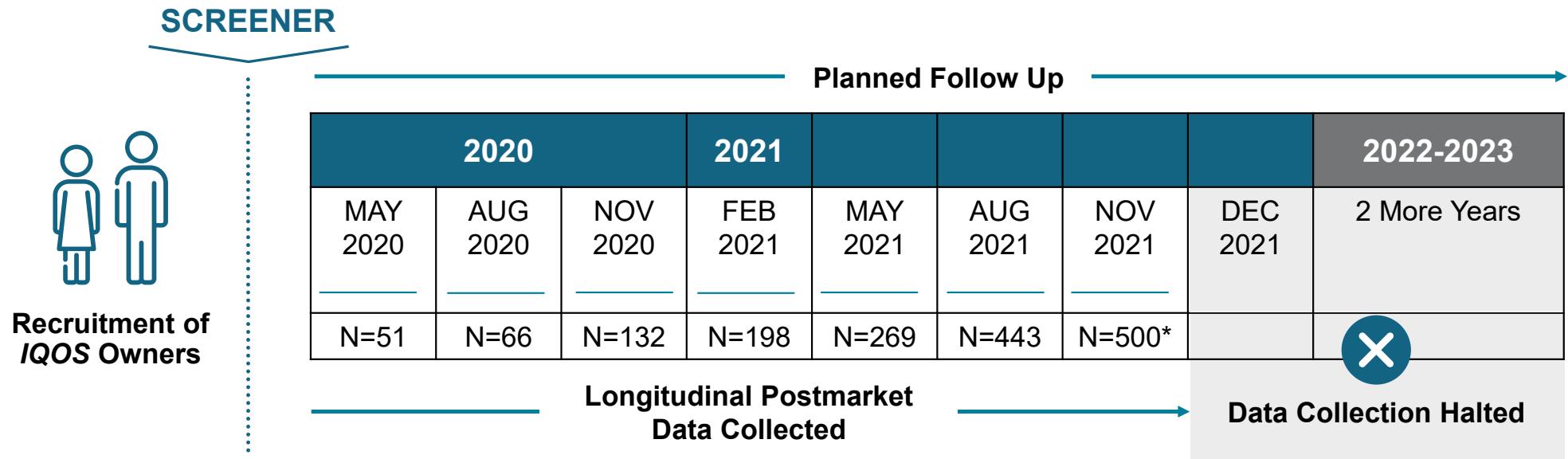


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**Correct response: "have less exposure to HPHCs".

Source: Cross-Sectional PACS

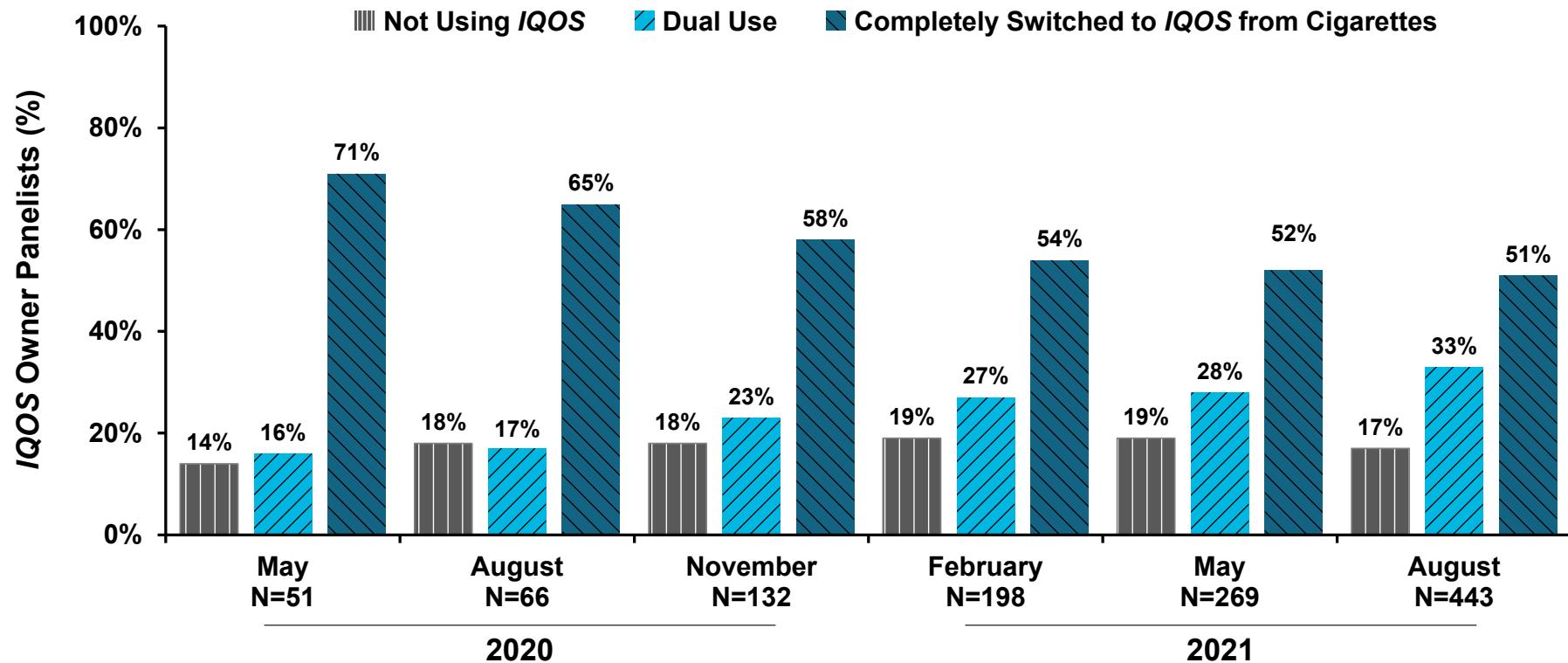
Study Design: IQOS Owners Panel



* On October 13th, 2021, an information letter was sent to study participants stating that IQOS would be unavailable for sale in the U.S. as of November 28th, 2021.
IQOS Owners: Adults who have purchased their IQOS device for 4 weeks or less prior to recruitment and who were using/smoking 3+ sticks per day at the time of recruitment.
Source: IQOS Owners Panel

Majority of IQOS Users Are Completely Switching from Cigarettes

Use Patterns



Data analysis limited due to the ITC decision and IQOS becoming unavailable on the U.S. market.

/QOS Owners: Adult who have purchased their IQOS device for 4 weeks or less prior to recruitment and who were using/smoking 3+ sticks per day at the time of recruitment.

Note: The sum of the percentages may not equal 100% due to rounding

Source: IQOS Owners Panel

FDA's Prior Conclusions

Youth Use



“

Current use patterns available for the authorized products within the U.S. ***have not raised concerns regarding product use in youth and young adults.***

”

— FDA 2023 PMTA TPL Review
(emphasis added)

Secondary Analysis: Underage Tobacco Use Survey (UTUS)



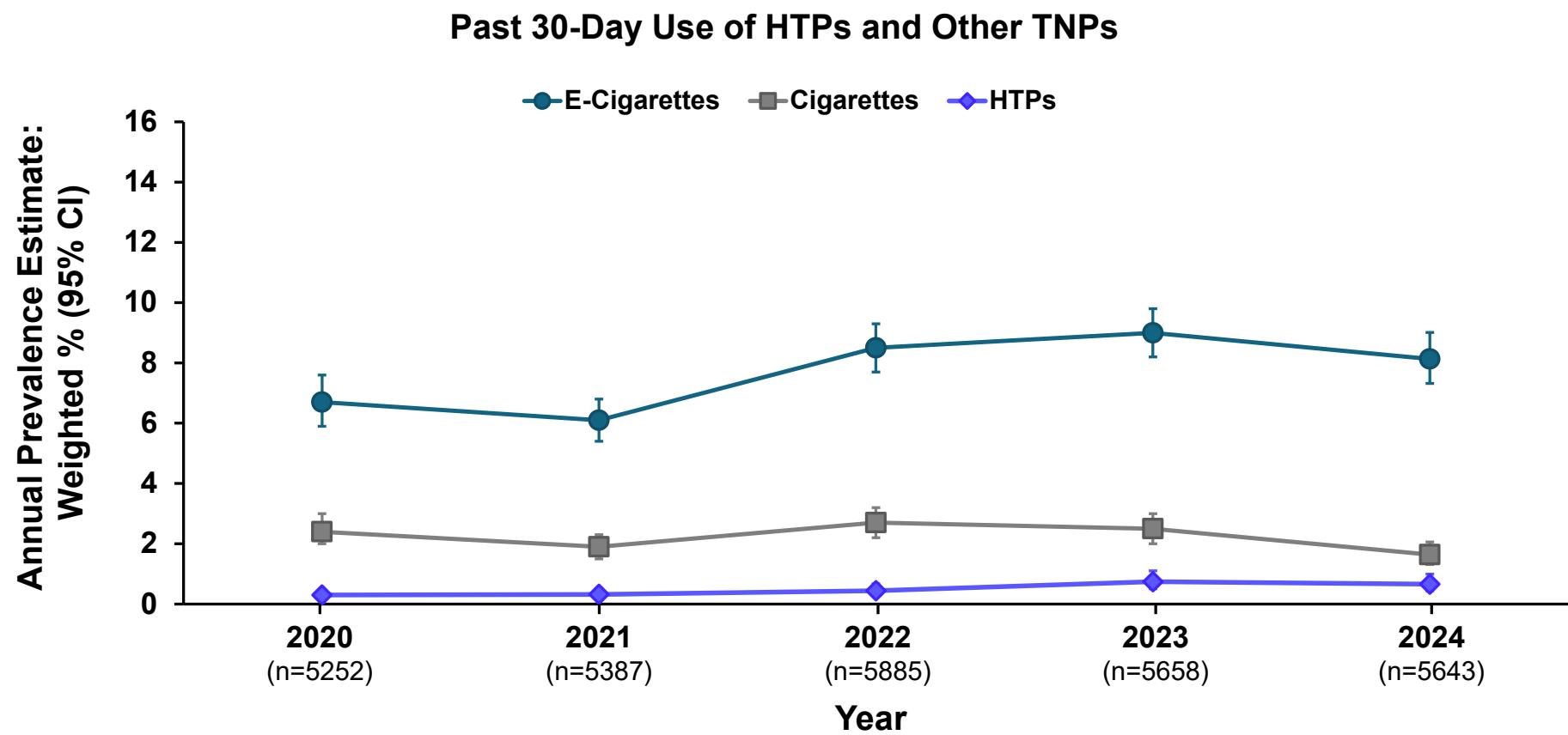
OBJECTIVES

Estimate:

1. Awareness of *IQOS*
2. Ever-use and past 30-day *IQOS* use
3. Lifetime use behavior
4. Past 30-day use behavior

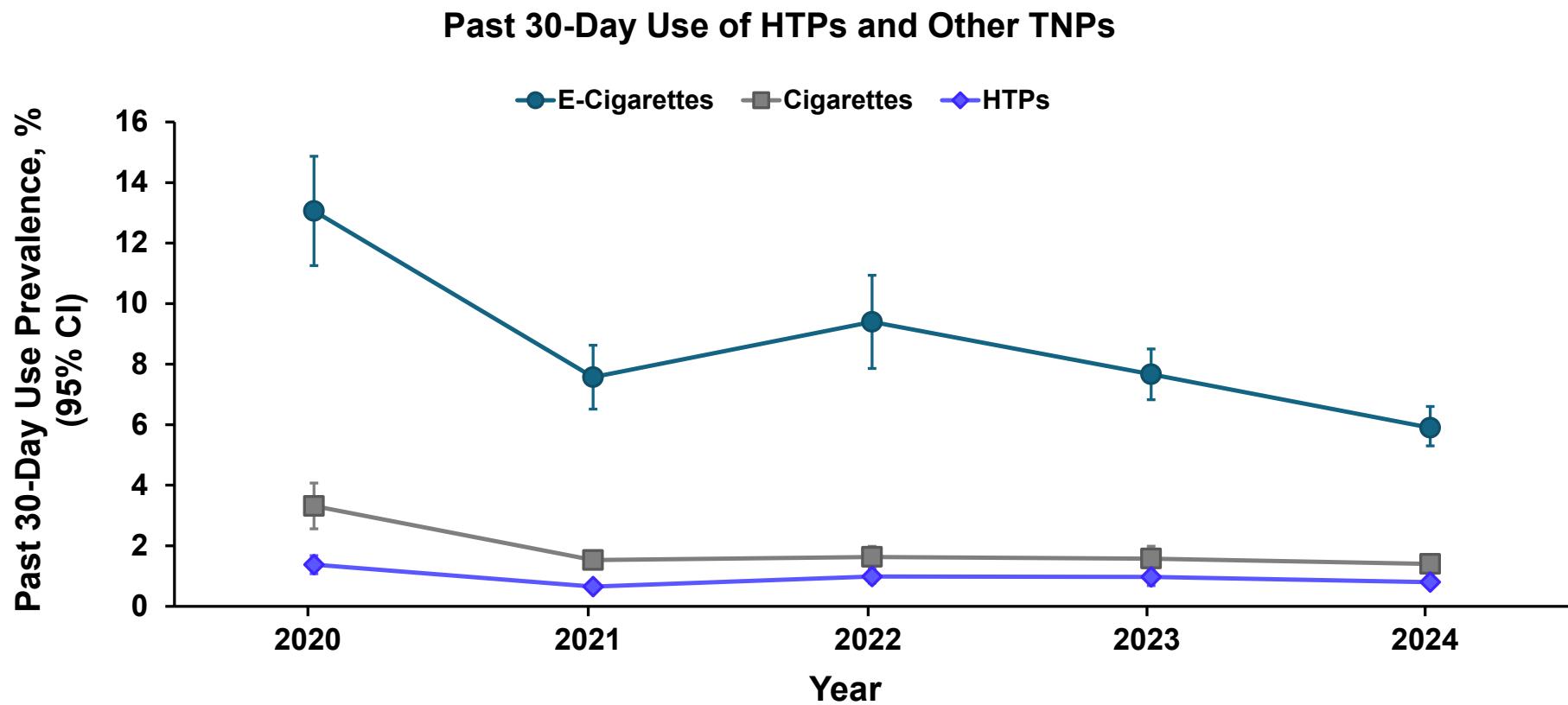
Q1 2020 Repeated Cross Sectional Design → Present

UTUS: Very Low HTP Use Prevalence in U.S. Youth



Source: UTUS 2020-2024 - US Youth in UTUS are individuals aged 13-20 years old

NYTS: Very Low HTP Use Prevalence in U.S. Youth



Sources: NYTS estimates calculated directly from public use data (https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/data/index.html) – US Youth in NYTS are middle school and high school students

Jamal A, Park-Lee E, Birdsey J, et al. Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024. *MMWR Morb Mortal Wkly Rep* 2024;73:917–924.
DOI: <http://dx.doi.org/10.15585/mmwr.mm7341a2>

Scientific Assessment Conclusions

POSTMARKET EVIDENCE

1 ***IQOS Continues to Significantly Reduce HPHC Exposure***

Estimated ~80% reduction in ELCRc

Up to 91% reduction in BoEs at 6 months

Significant favorable difference in eight core BoPHs

2 ***Consumers Continue to Understand the Reduced Exposure Claim***

- HPHC exposure is reduced when switching completely from cigarettes to *IQOS*
- Smokers must switch completely from cigarettes to *IQOS* to reduce their exposure to HPHCs

3 ***IQOS Users Switch From or Reduce Cigarette Use***

>50% No longer smoke cigarettes

83% reduced their CPD

4 ***IQOS Use Among Youth is Very Low***

Negligible use when *IQOS* was commercialized

Responsible Marketing and Controls

JB Simko

Vice President and U.S. Chief Underage Prevention Officer

Marketing and Controls

1

Intended Audience

2

Underage Prevention

3

Use of Reduced Exposure Claim

Adults 21+



OUR INTENDED AUDIENCE



Tobacco and Nicotine
Product Consumers



1 Build Awareness

2 Product Trial

3 Conversion

Responsible Marketing Practices

Brand website access limited to ONLY those confirmed to be 21+	
Brand website access limited to self-reported current users of TNP	
Brand website e-commerce limited to U.S. states where IQOS is sold	
All models and talent are over the age of 35	
We do NOT advertise in publications for general circulation unless its audience is reasonably estimated to be at least 85% adults (21+)	
We do NOT engage via email/direct mail with any consumers who aren't confirmed to be 21+	
We do NOT have branded social media advertising accounts on platforms without age-restriction controls	
We do NOT pay social media influencers to endorse our products	

Age-Verification at IQOS Point-of-Sale

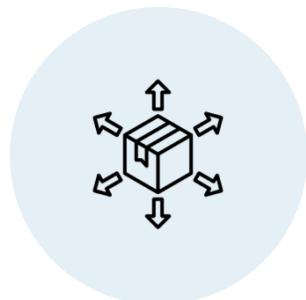
Face-to-Face



E-Commerce



Use of Reduced Exposure Claim



Device packaging
IQOS 3.0



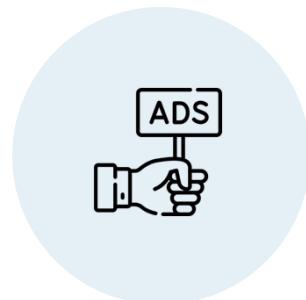
Digital Property
Brand website



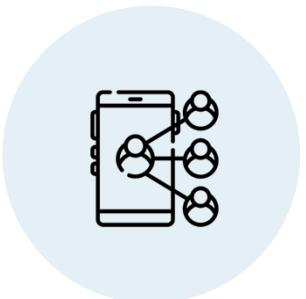
Point-of-Sale
Face-to-face & e-commerce



Email & Direct Mail
to 21+ age-verified consumers



Print & Digital Ads
where at least 85% are age 21+



Shared Digital Properties
Social media

Examples of Marketing Materials

BUILD AWARENESS

Print and Digital Advertising



PRODUCT TRIAL In-Store Brochure



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

*PMI Financials or estimates, IQOS user panels and PMI Market Research as of October 2024.

CONVERSION Device Packaging



IQOS significantly reduces the production of harmful & potentially harmful chemicals

IQOS system heats tobacco but does not burn it.

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.

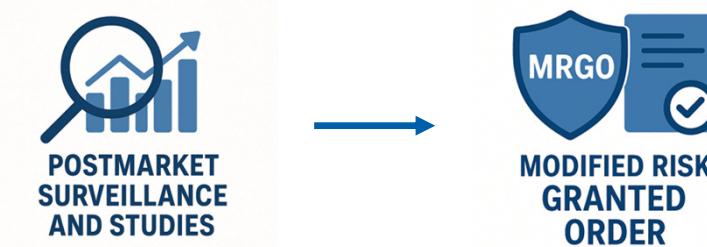
Conclusion

Keagan Lenihan

Vice President and Chief External Affairs Officer, US

Collective Evidence Supports MRTP Renewal

Since 2020, PMSS requirements have been fulfilled with no change to MRGO status



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The evidence and data continues to demonstrate the harm reduction potential of IQOS with the reduced exposure claim



***IQOS MODIFIED RISK GRANTED ORDERS
SHOULD BE RENEWED***



IQOS 2.4, IQOS 3.0, and HEETS MRTP Renewal

PMI U.S.

Tobacco Products Scientific Advisory Committee Meeting
October 7th, 2025

Backup slide shown

ERS Extension Study – Nicotine Exposure

