



# ***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**

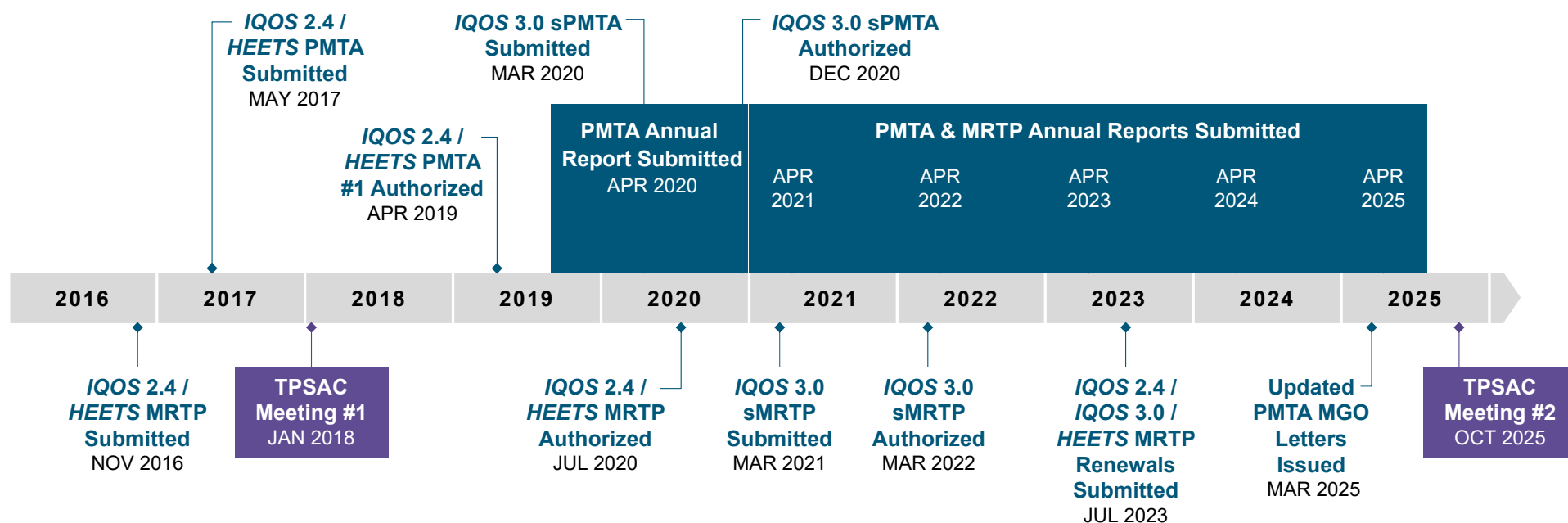


**HEETS consumables**



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 /QOS 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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- IQOS, as actually used by consumers, has the potential to significantly reduce tobacco product users' exposure to harmful and potentially harmful constituents
- Consumers understand the relative risk of IQOS compared to cigarettes, and the need to switch completely

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- IQOS, when marketed with the reduced exposure claim, promotes complete switching and reduction in cigarette consumption

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



“

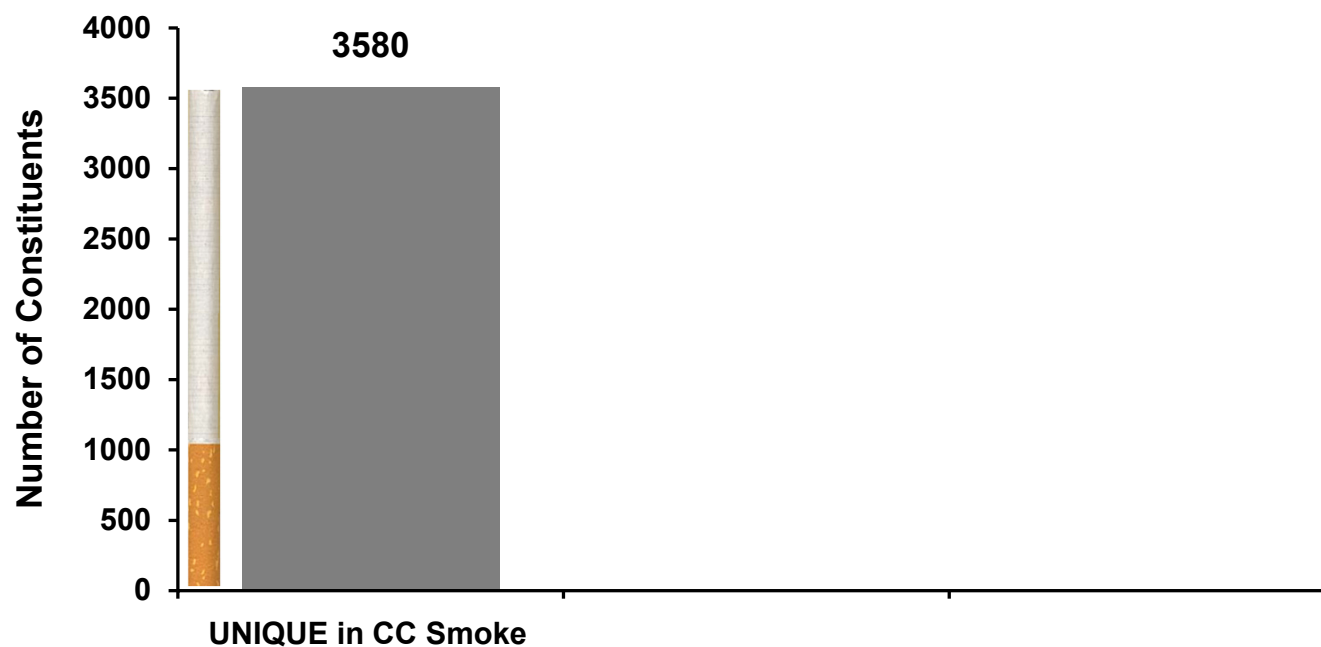
When assessing the overall yield of chemicals...the yields of potential carcinogens, respiratory toxicants, and reproductive/developmental toxicants were ***considerably lower in Heatstick aerosols*** compared with combusted cigarette smoke.

”

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

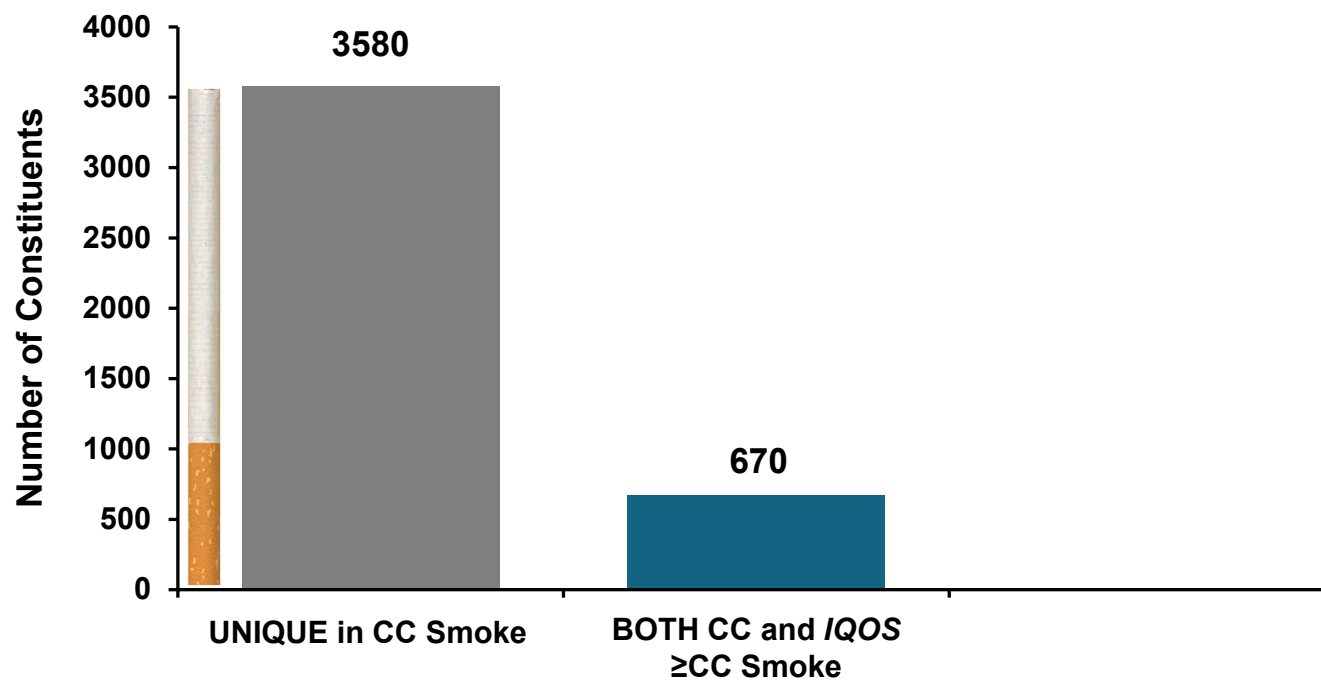


# NTDS: Comparison of Cigarette Smoke and IQOS Aerosol



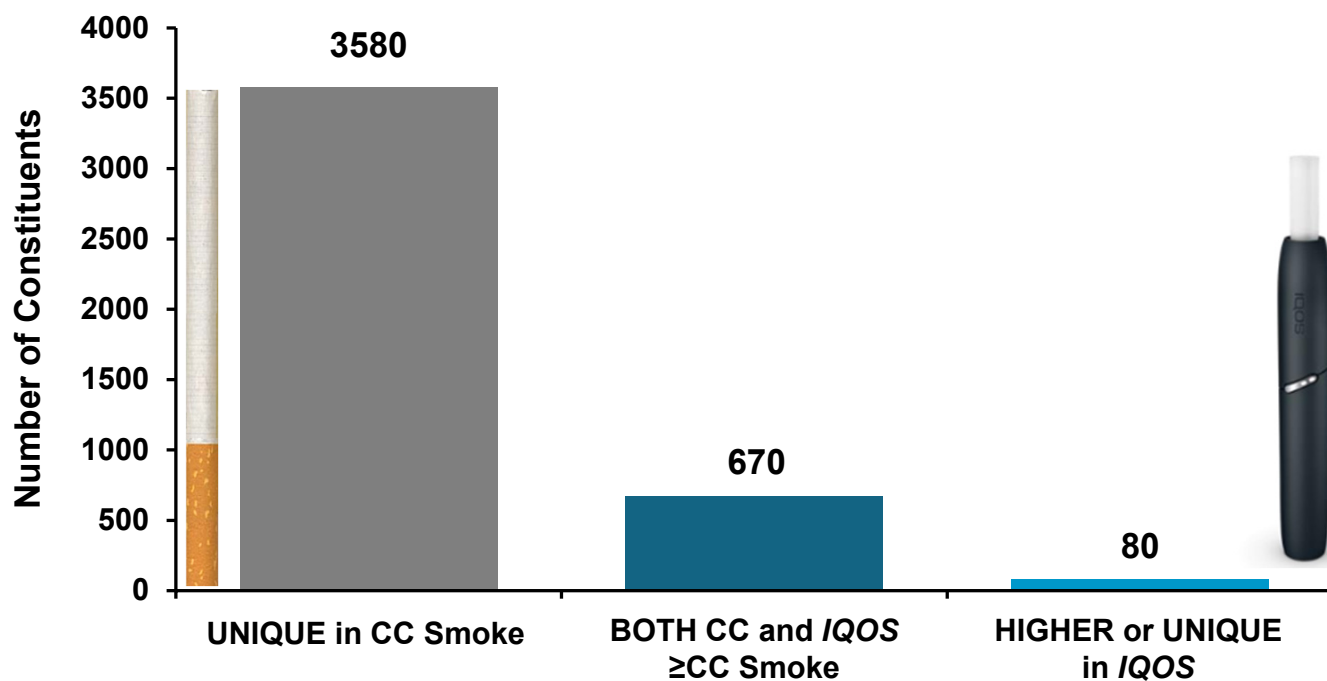
CC = Combusted Cigarette  
Constituents were present in >100ng/stick  
Source: PMSS- Computational Toxicology Report

# NTDS: Comparison of Cigarette Smoke and IQOS Aerosol



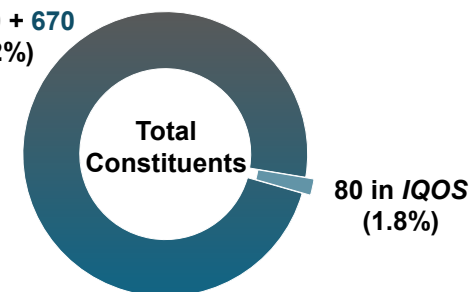
CC = Combusted Cigarette  
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Source: PMSS- Computational Toxicology Report

# NTDS: Comparison of Cigarette Smoke and IQOS Aerosol



## CC Compared to IQOS

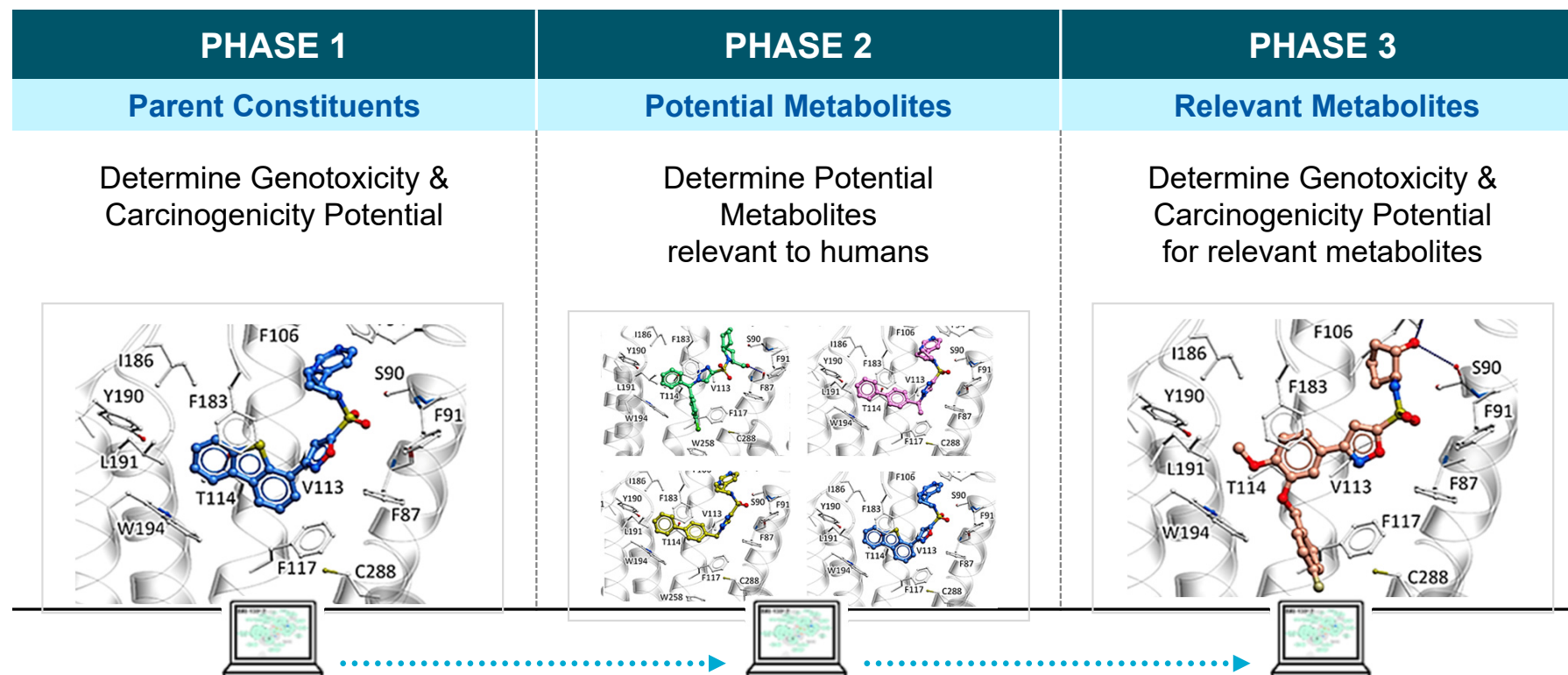
4250 in CC Smoke  
3580 + 670  
(98.2%)



✓ SMALL NUMBER AND  
LOW LEVELS OF  
IQOS CONSTITUENTS  
**OUTWEIGH CONCERNS**

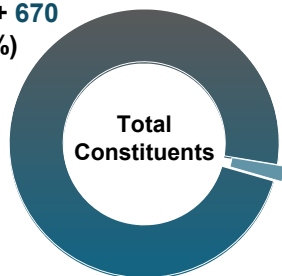
CC = Combusted Cigarette  
Constituents were present in >100ng/stick  
Source: PMSS- Computational Toxicology Report

# Study Design: Computational Toxicology Assessment



# Parent Constituents: Genotoxic and Carcinogenic Potential

4250 in CC Smoke  
3580 + 670  
(98.2%)



80 (1.8%)  
Parent  
Constituents  
in *IQOS*

Non-Toxic\*

44

Potentially Toxic

36

Initial output and prediction  
confidence assessment

Potentially  
Genotoxic

Potentially  
Carcinogenic

High Predictive  
Confidence

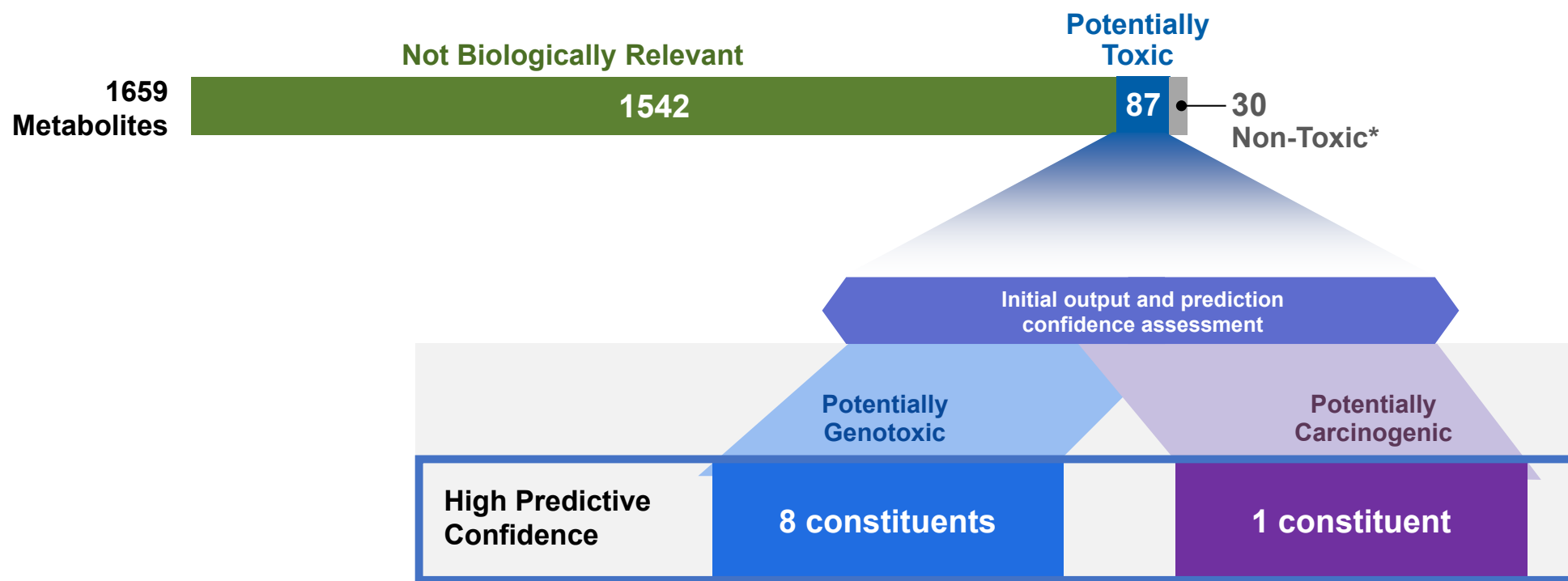
5 constituents

6 constituents

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

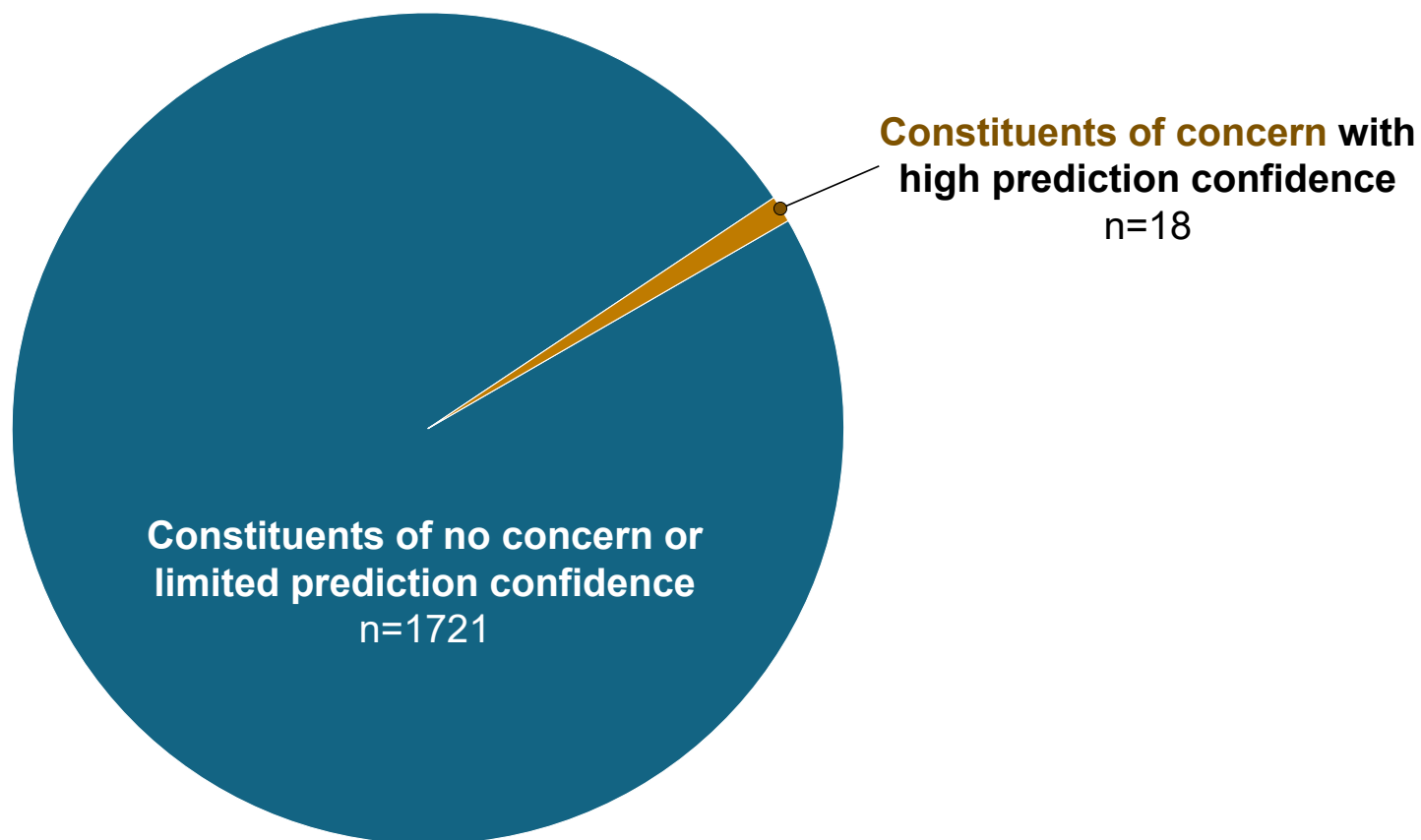
CC-21

# Parent Constituents' Metabolites: Genotoxic and Carcinogenic Potential

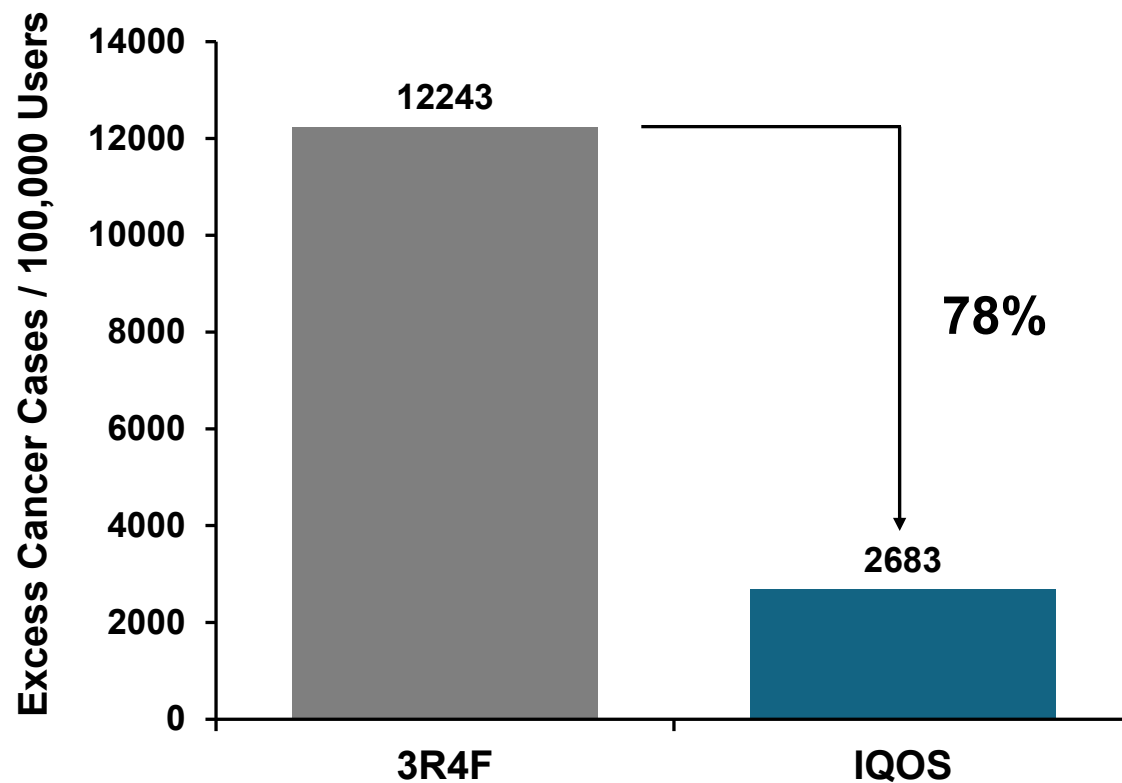


\*Regarding assessments of genotoxicity and carcinogenicity  
Source: PMSS- Computational Toxicology Report

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



# Estimation of $ELCR_c$ for IQOS Aerosols vs. 3R4F Smoke





# FDA's Prior Conclusions

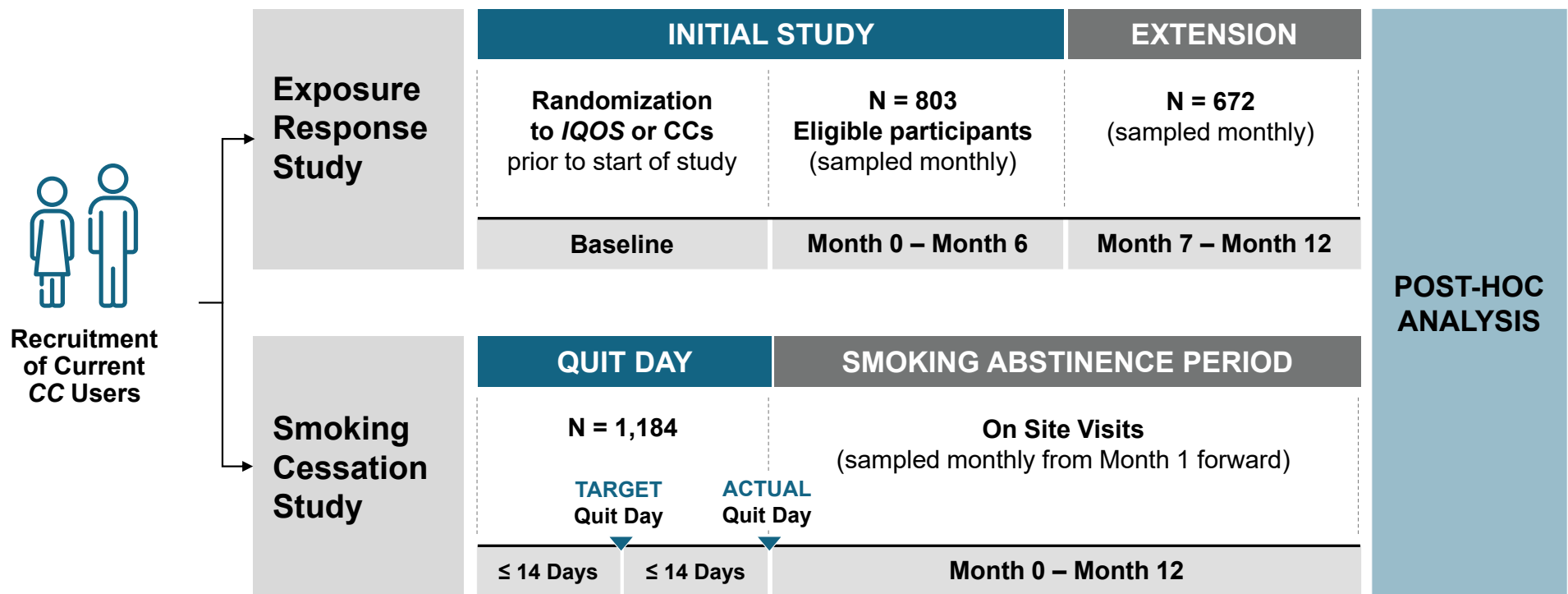
## BOEs



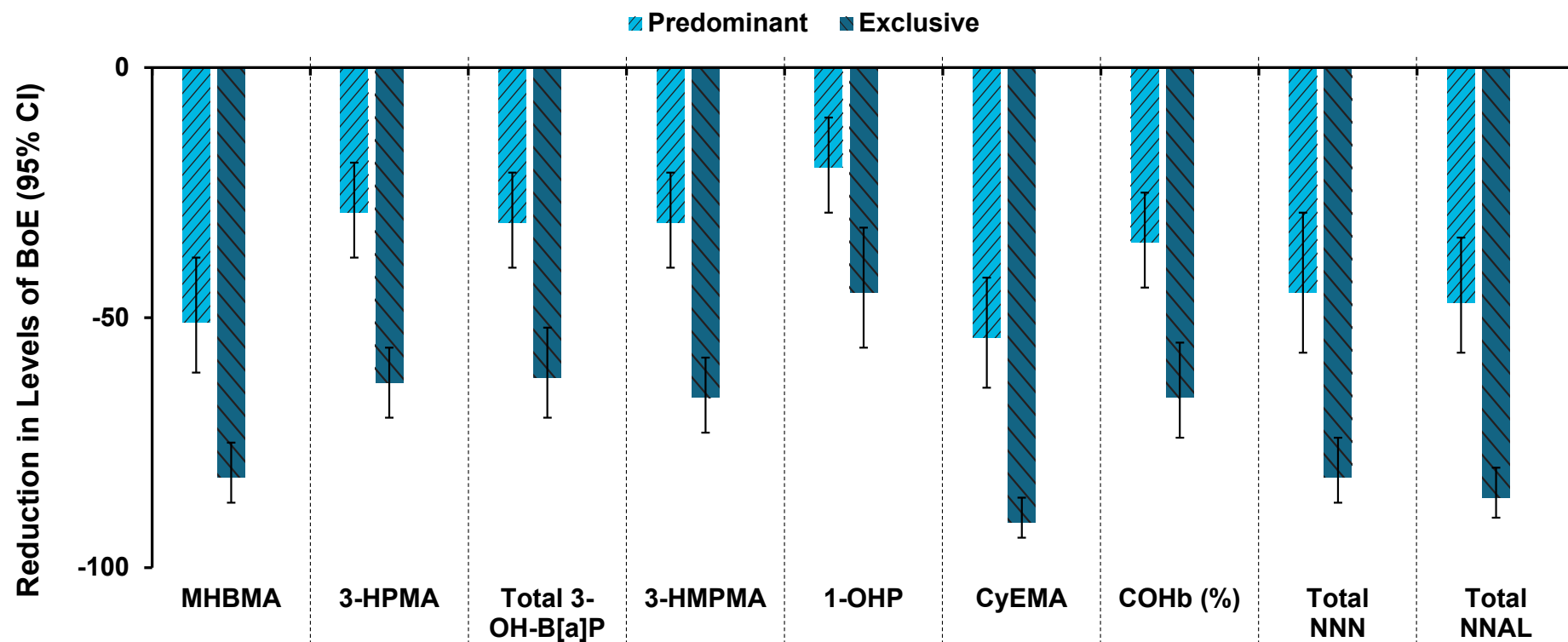
“ Findings from the clinical studies suggest a ***significant reduction in BOEs to 15 HPHCs when smokers switch completely to IQOS.*** The reduced BOEs reflect a range of chemical and toxicity classes. ”

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

## Study Design: Additional Studies Assessing BOEs



# Changes in BOEs with IQOS Use vs Smoking at 6 Months



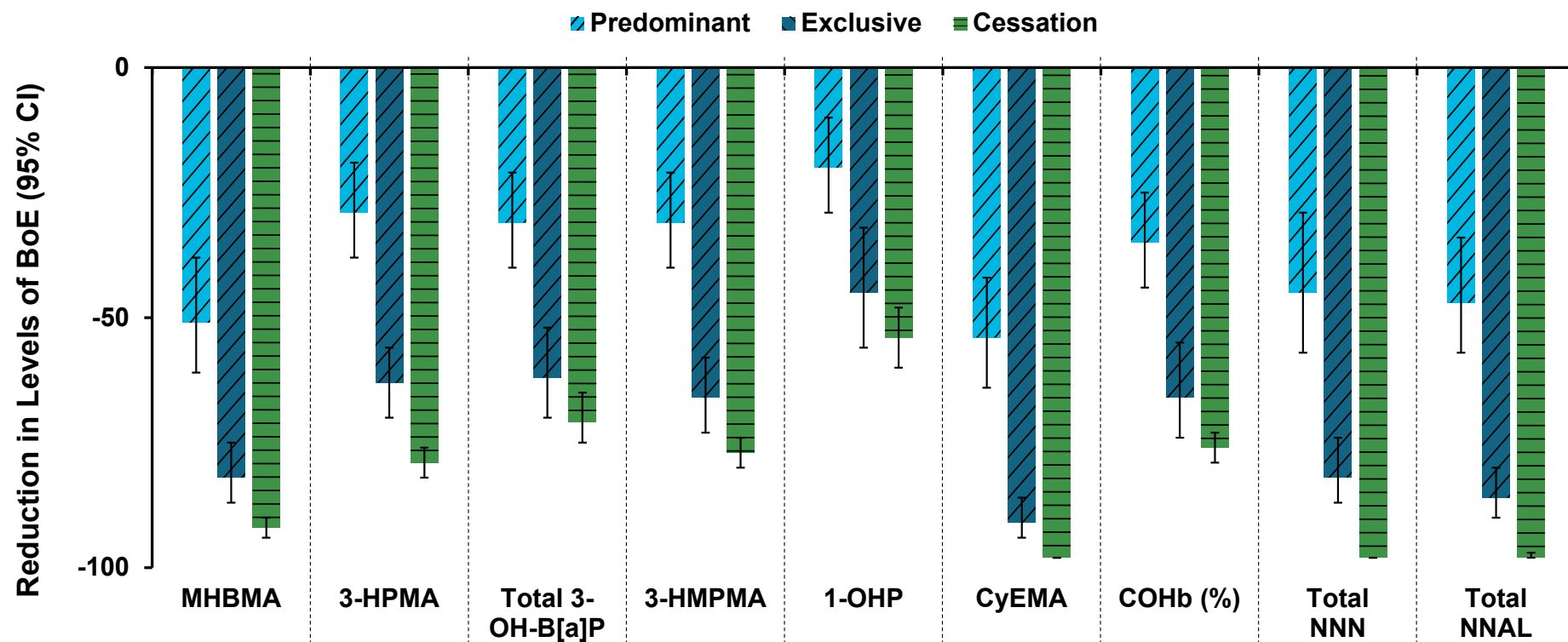
All results shown were statistically significant

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-Nitrosonornicotine; 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



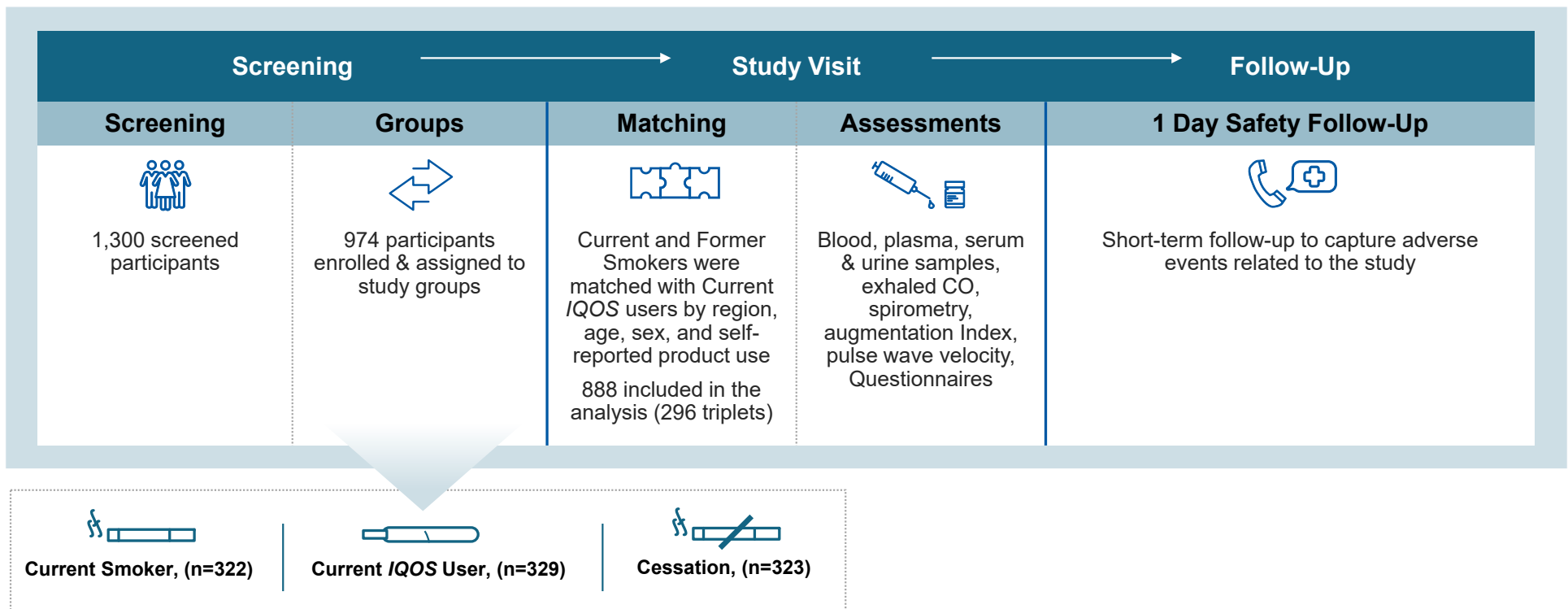
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MHBMA: Monohydroxy-3-butenyl mercapturic acid; 3-HPMA: 3-Hydroxypropylmercapturic acid; 3-OH-B[a]P: 3-Hydroxybenzo[a]pyrene;

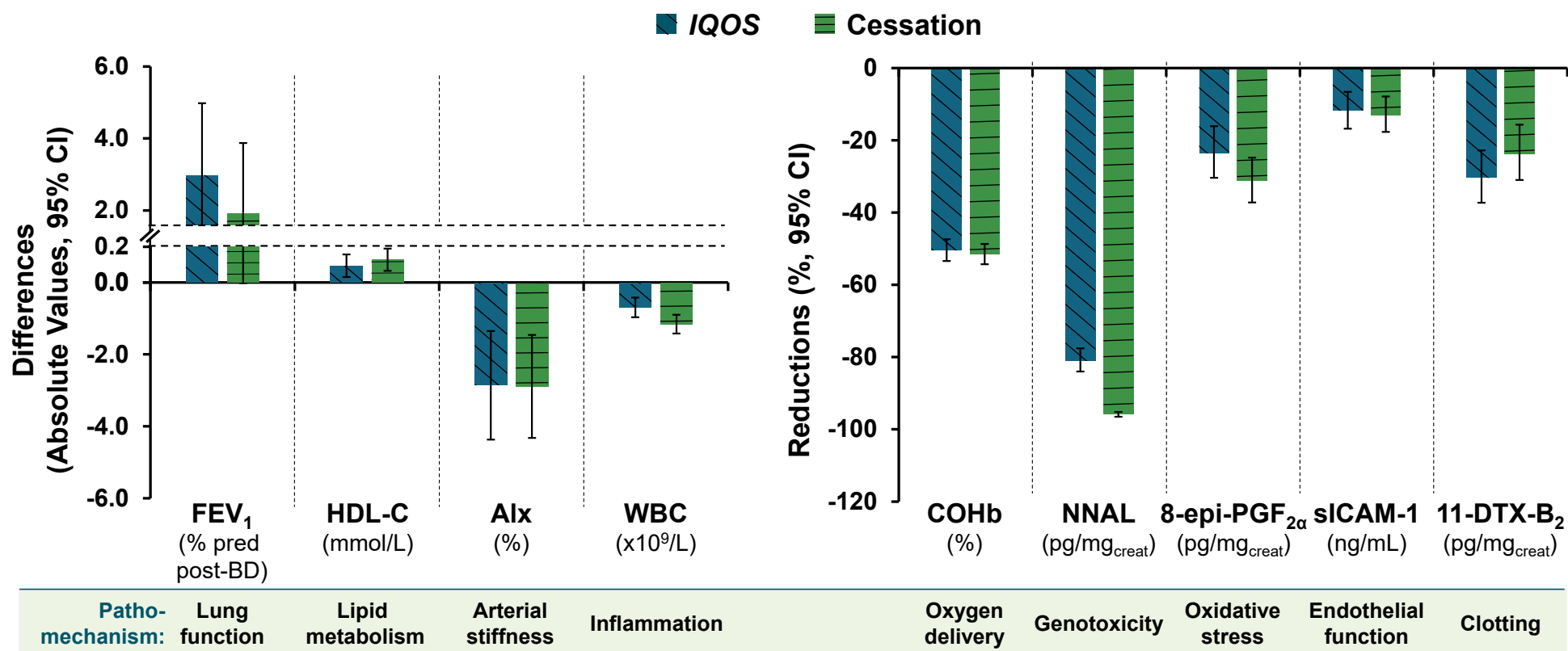
3-HMPMA: 3-Hydroxy-1-ethylpropylmercapturic acid; 1-OHP: 1-Hydroxypyrene; NNN: N-Nitrosomonicotine; 2CyEMA: 2-Cyanoethylmercapturic acid

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-B<sub>2</sub>: 11-dehydrothromboxane B<sub>2</sub>; 8-epi-PGF<sub>2α</sub>: 8-epi-prostaglandin-F<sub>2α</sub>; FEV<sub>1</sub> %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-(methylnitrosamino)-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



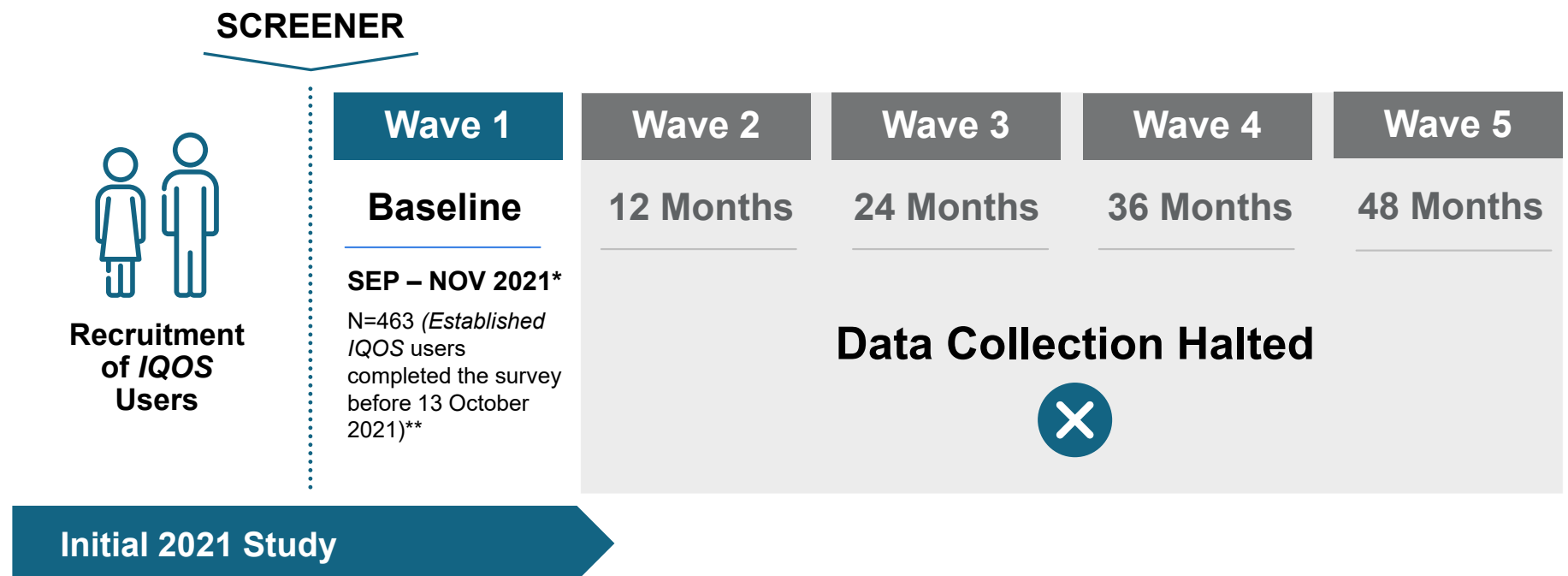
“

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.

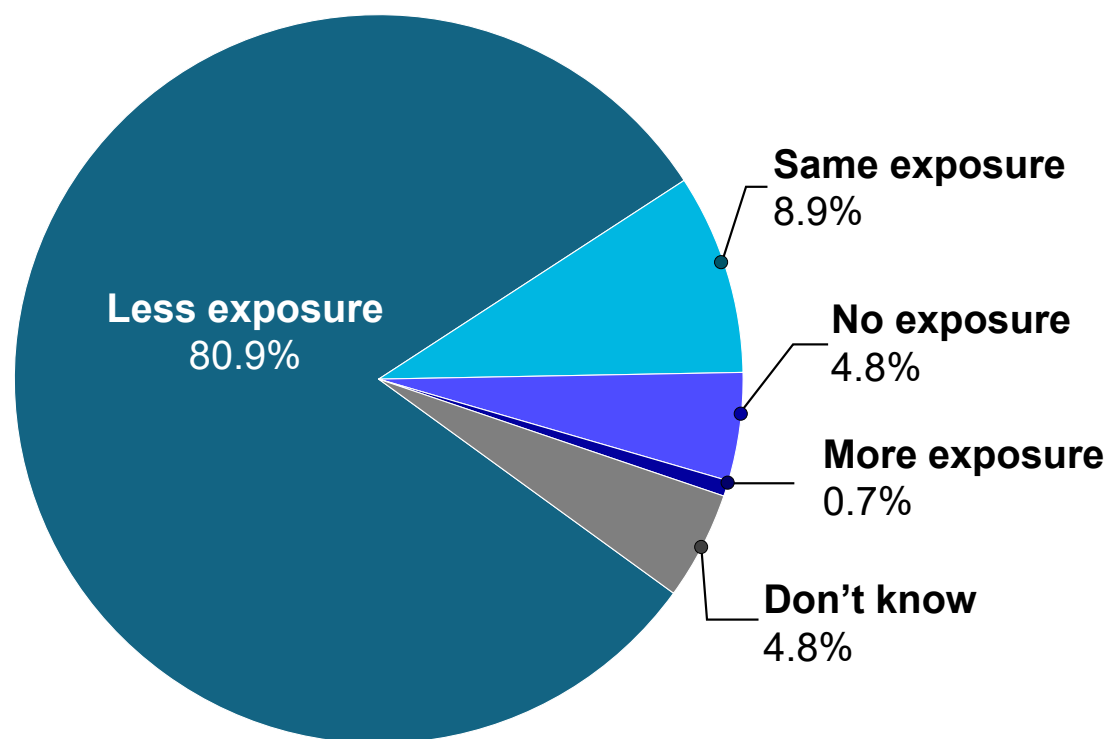
\*\* Established IQOS users defined as reporting having ever used IQOS and having used 100 or more HEETS in their lifetime.

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

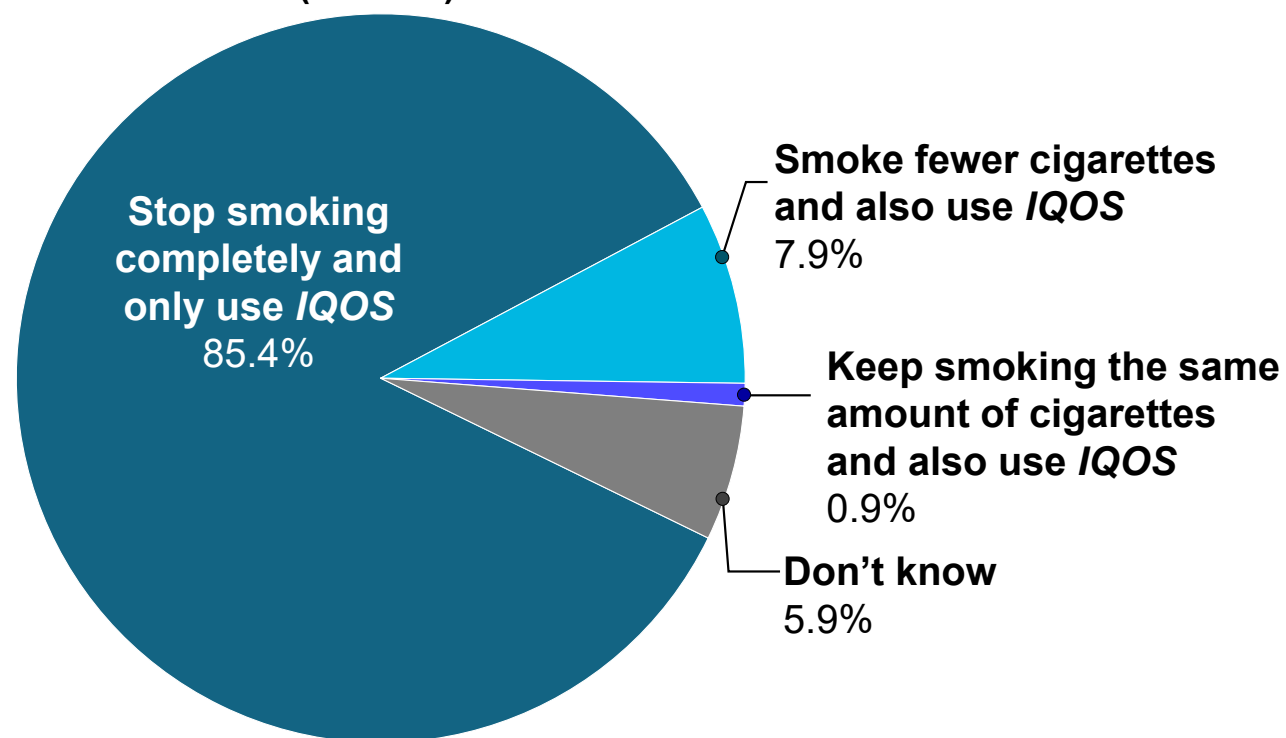
Note: The sum of the percentages may not equal 100% due to rounding

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

Current IQOS Users  
(N=355\*)



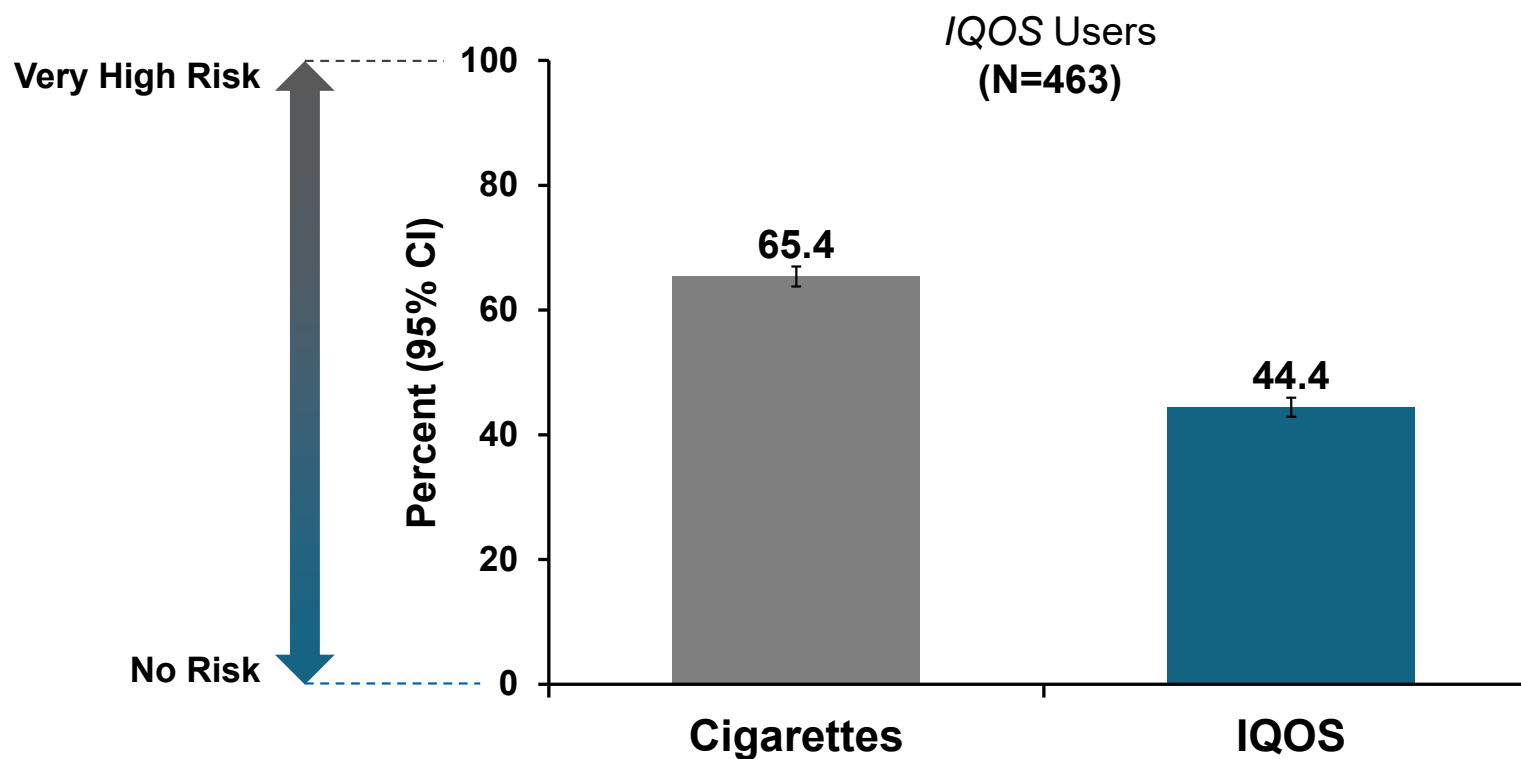
\*This question was asked of only those respondents who correctly identified that using IQOS instead of cigarettes reduces their exposure to harmful or potentially harmful chemicals.

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



“

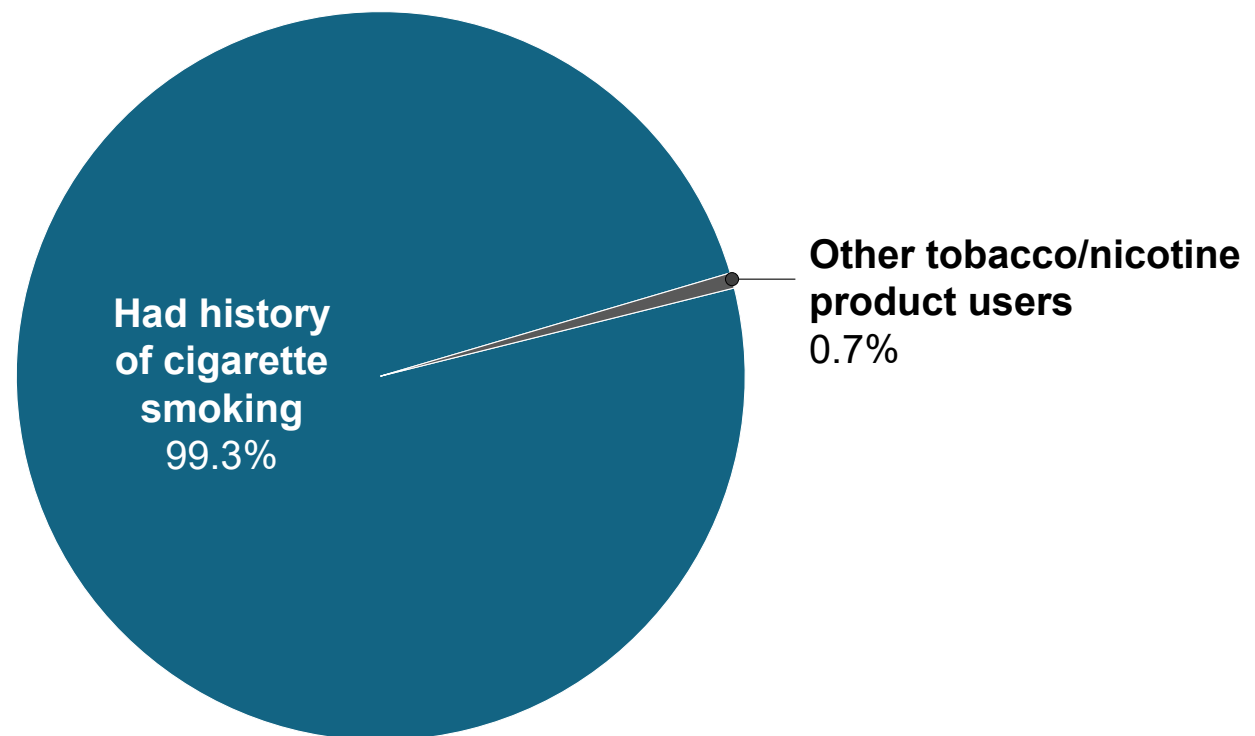
Marketing IQOS with a reduced exposure claim could ***appeal to current smokers who are most likely to benefit from their use***, and this supports a likely benefit to population health.

”

*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.

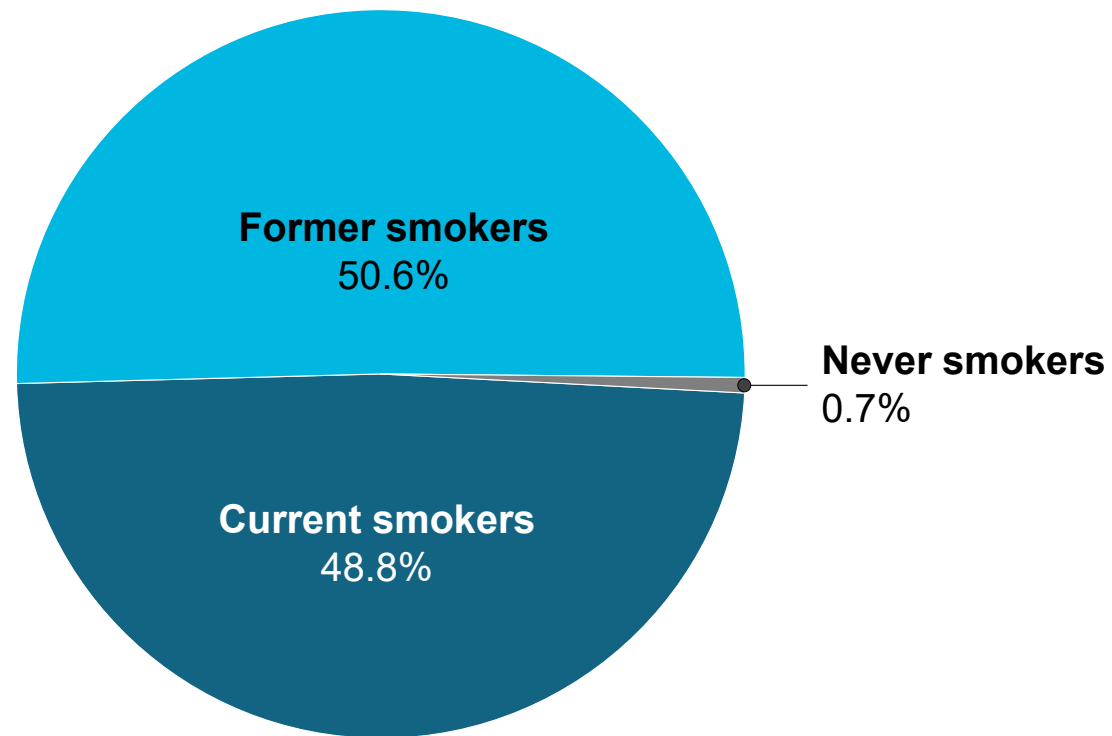
TNP = Tobacco or Nicotine Products

Source: Cross-Sectional PACS



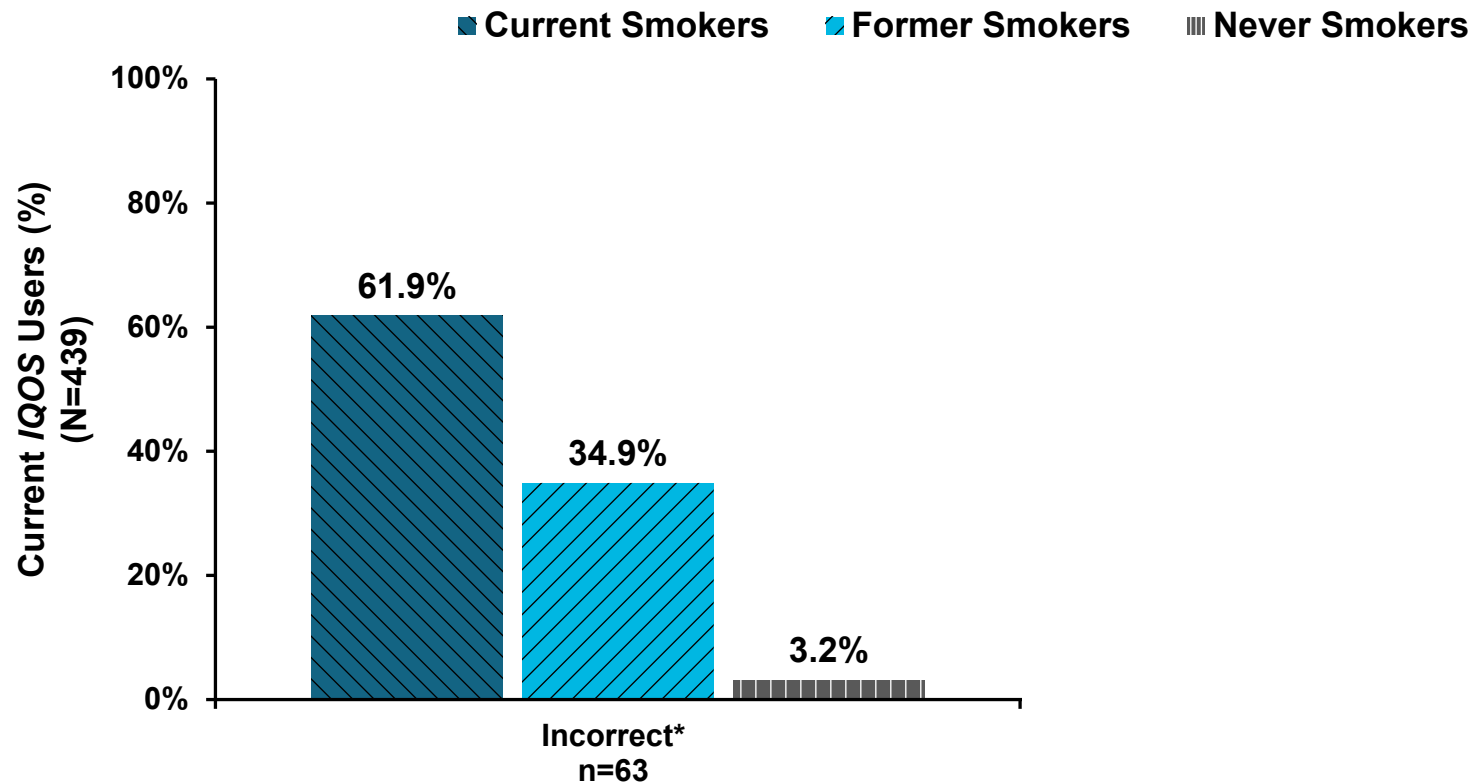
# ***IQOS* Users are Switching from Cigarette Smoking**

**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

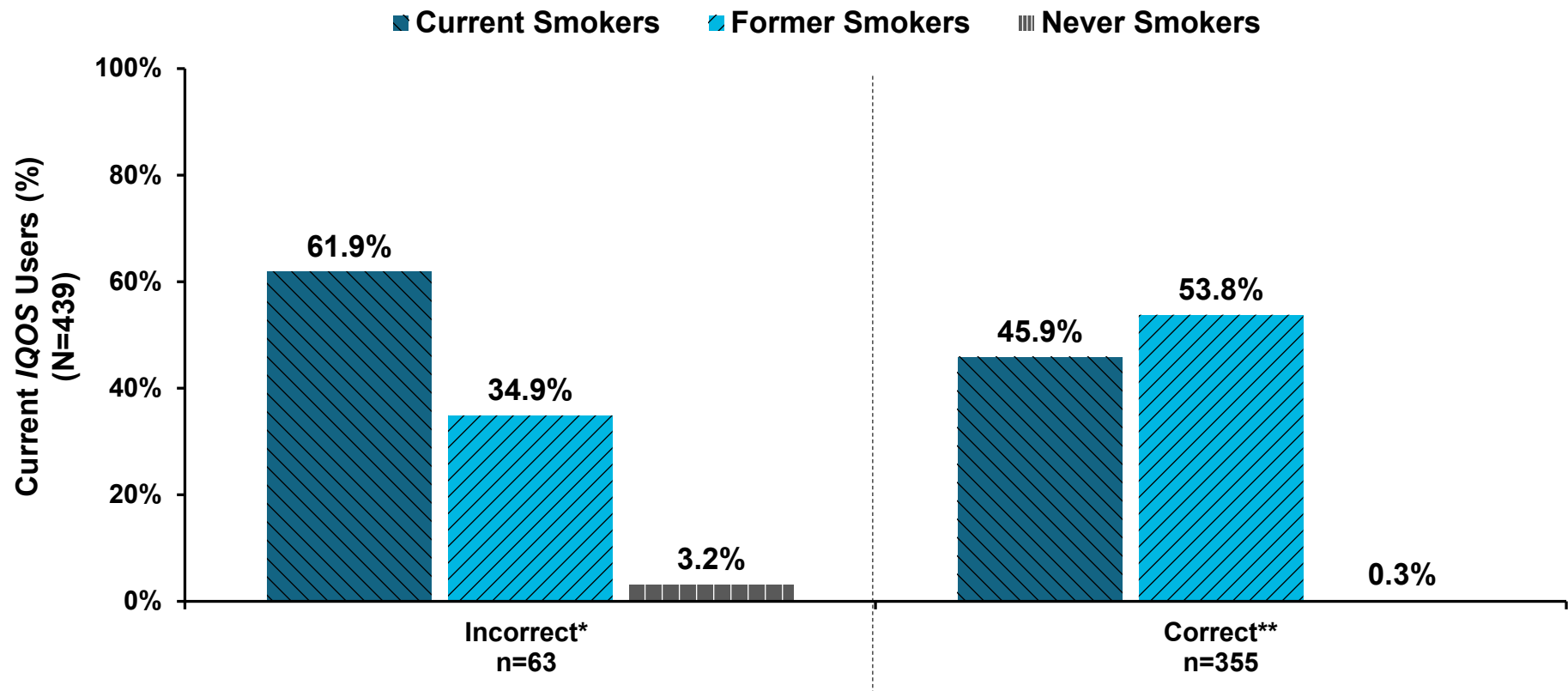


\* Incorrect responses include "have more exposure to HPHCs", "have the same exposure to HPHCs", and "have no exposure to HPHCs". This analysis does not include "don't know" (n=21).

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

Source: Cross-Sectional PACS

# Cigarette Smoking Status According to Understanding of Reduced Exposure to HPHCs



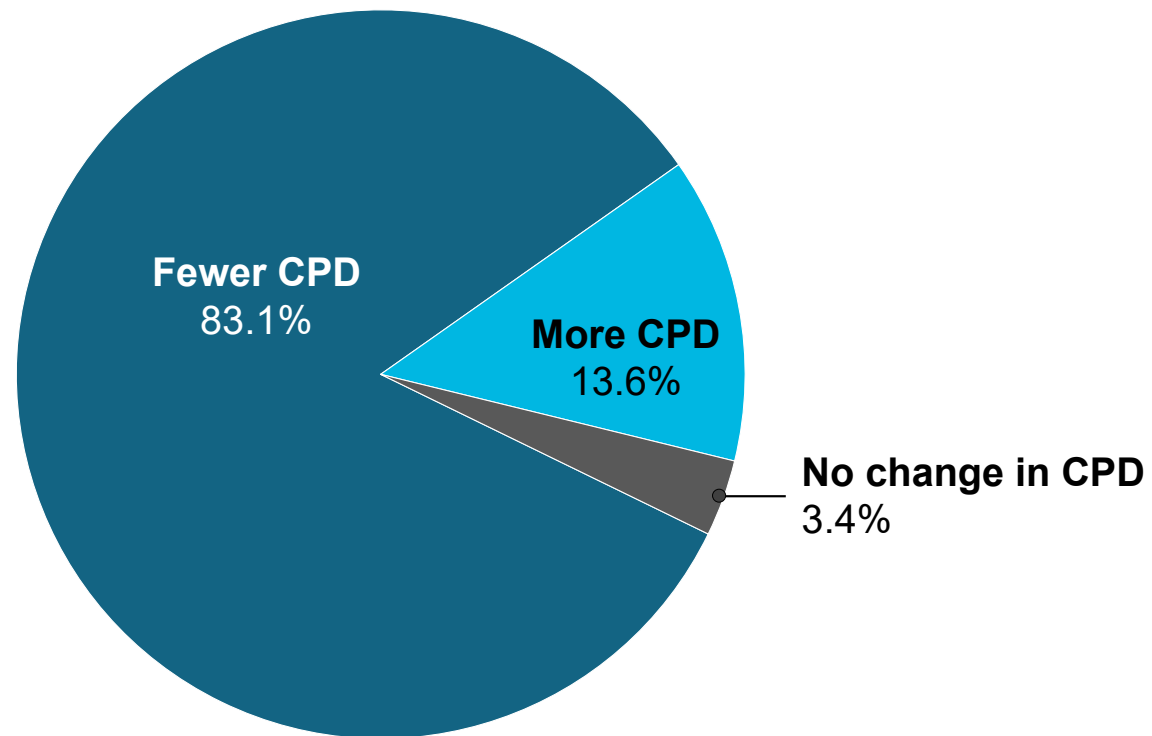
\* Incorrect responses include "have more exposure to HPHCs", "have the same exposure to HPHCs", and "have no exposure to HPHCs". This analysis does not include "don't know" (n=21).

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

Source: Cross-Sectional PACS

# ***/*QOS Users are Reducing their Cigarette Consumption**

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



CPD = Cigarettes Per Day

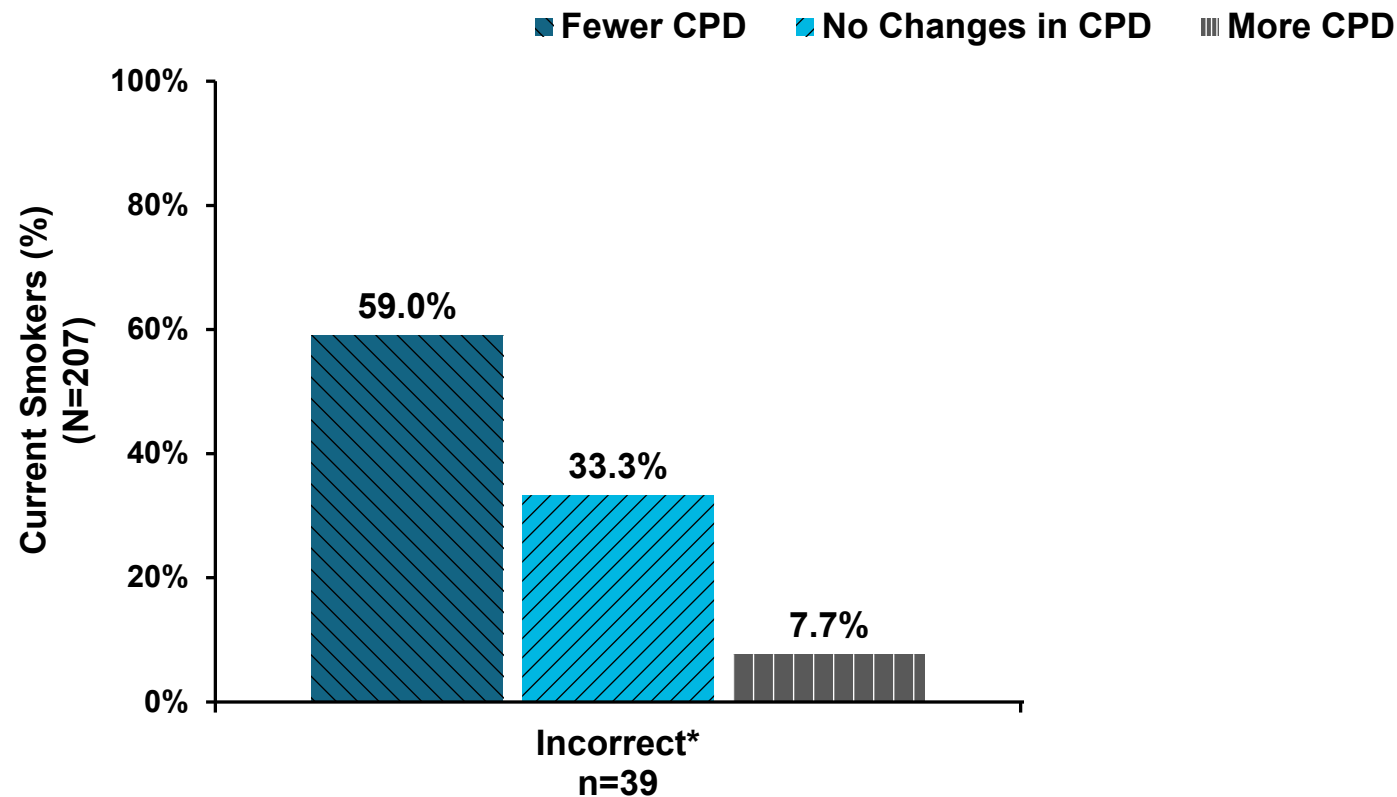
\*Compared to the 30 days before the first trial of */*QOS.

\*\* 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

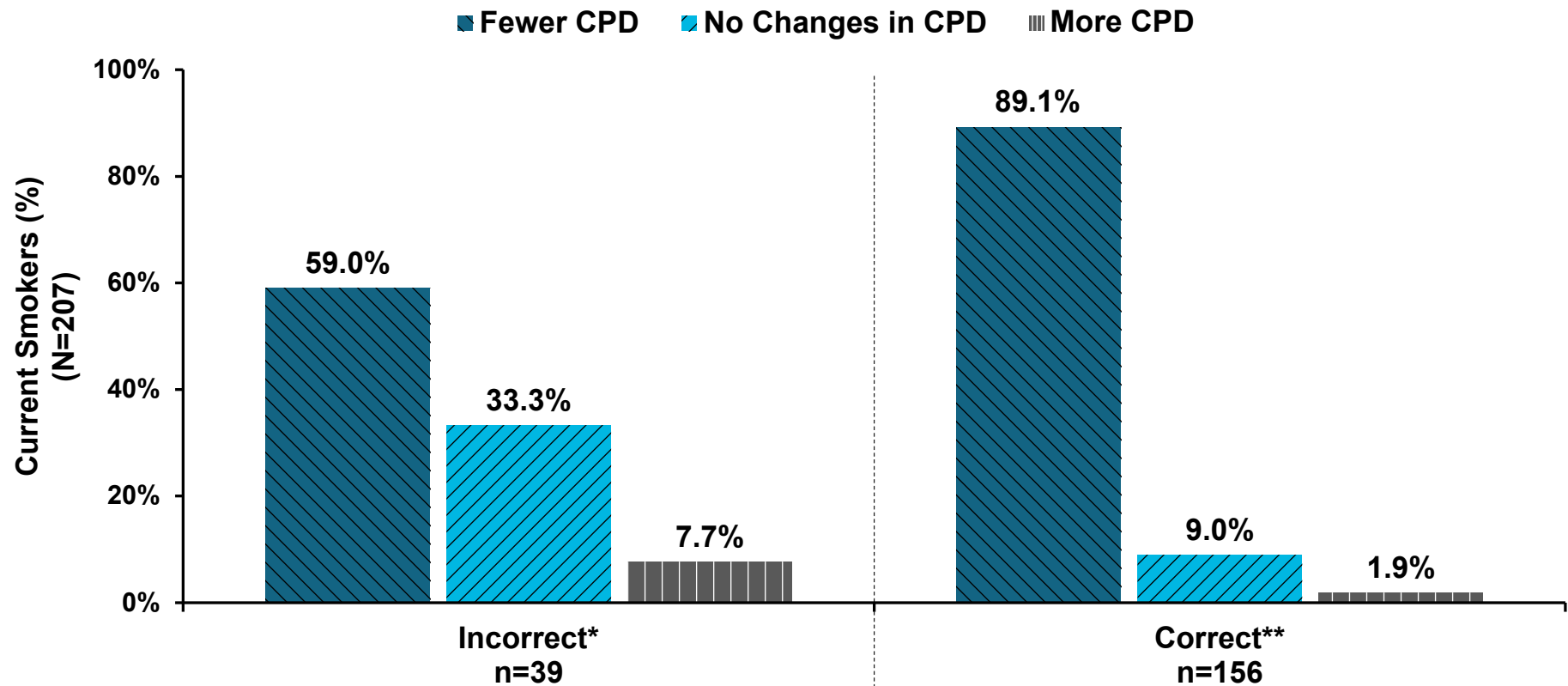


\*Incorrect responses include "have more exposure to HPHCs", "have the same exposure to HPHCs", and "have no exposure to HPHCs". This analysis does not include "don't know" (n=12).

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

Source: Cross-Sectional PACS

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

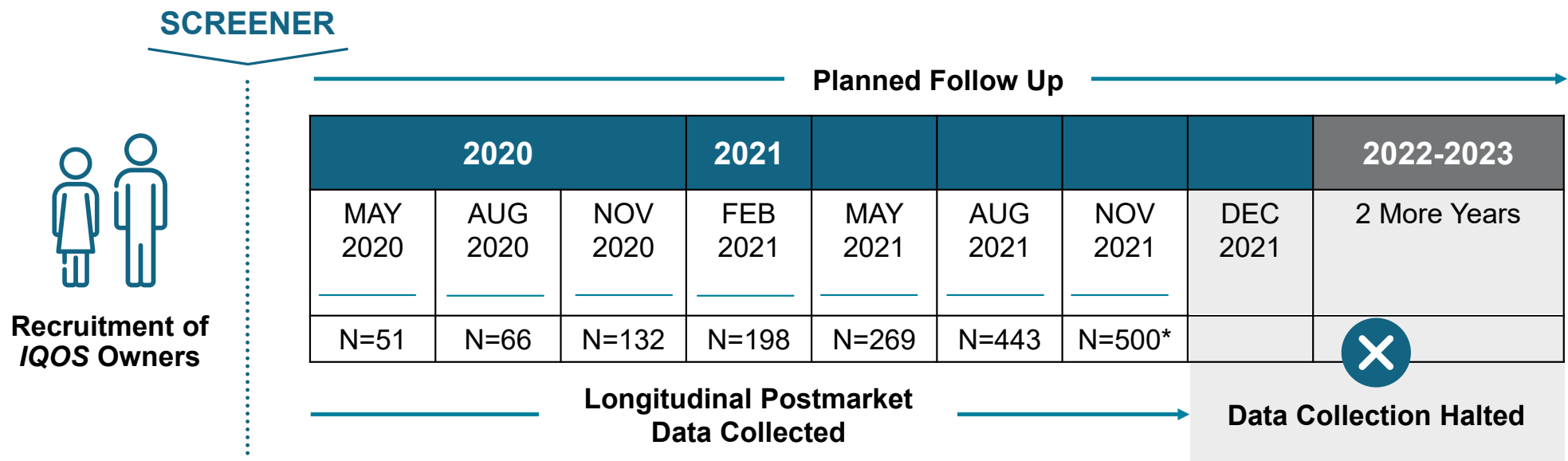


\*Incorrect responses include "have more exposure to HPHCs", "have the same exposure to HPHCs", and "have no exposure to HPHCs". This analysis does not include "don't know" (n=12).

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

Source: Cross-Sectional PACS

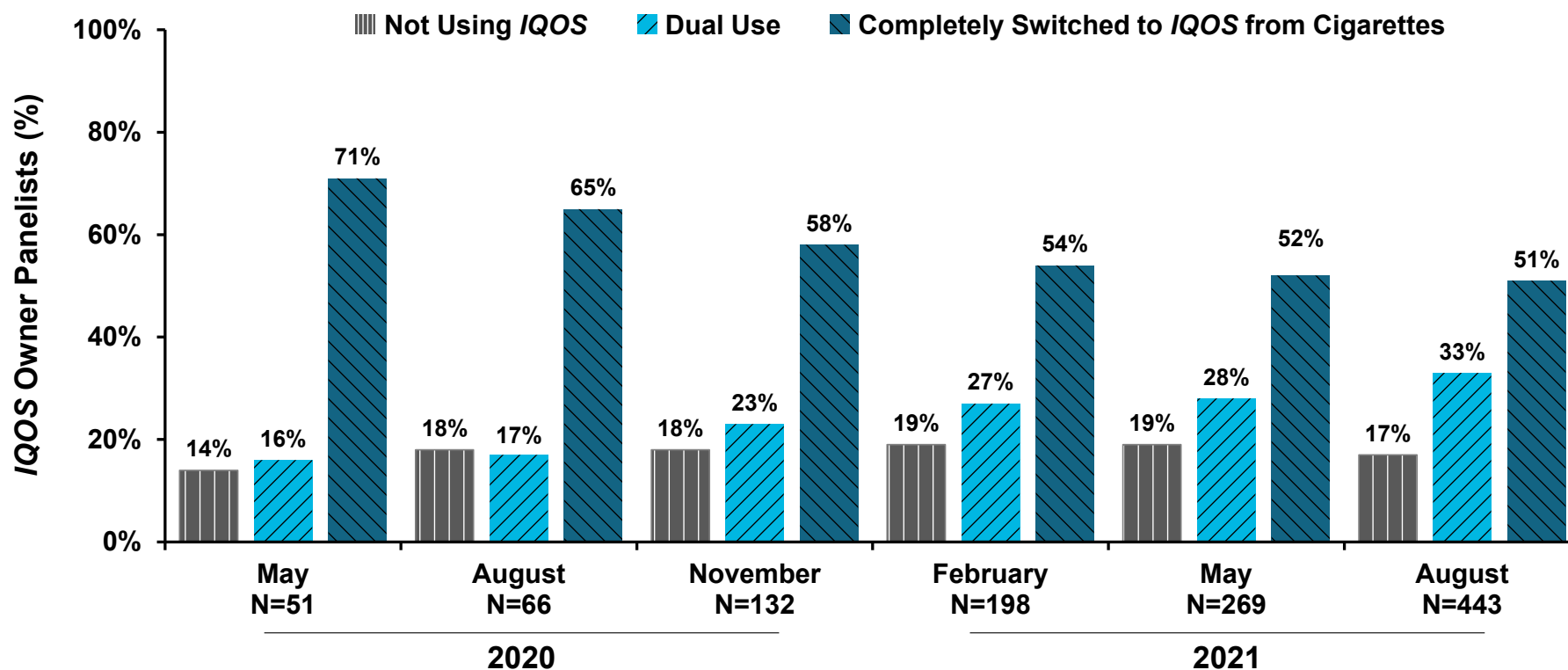
# Study Design: IQOS Owners Panel



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



Individuals  
13-20 years old  
living in the U.S.

**TARGET:**  
n = 5,000 annually

## OBJECTIVES

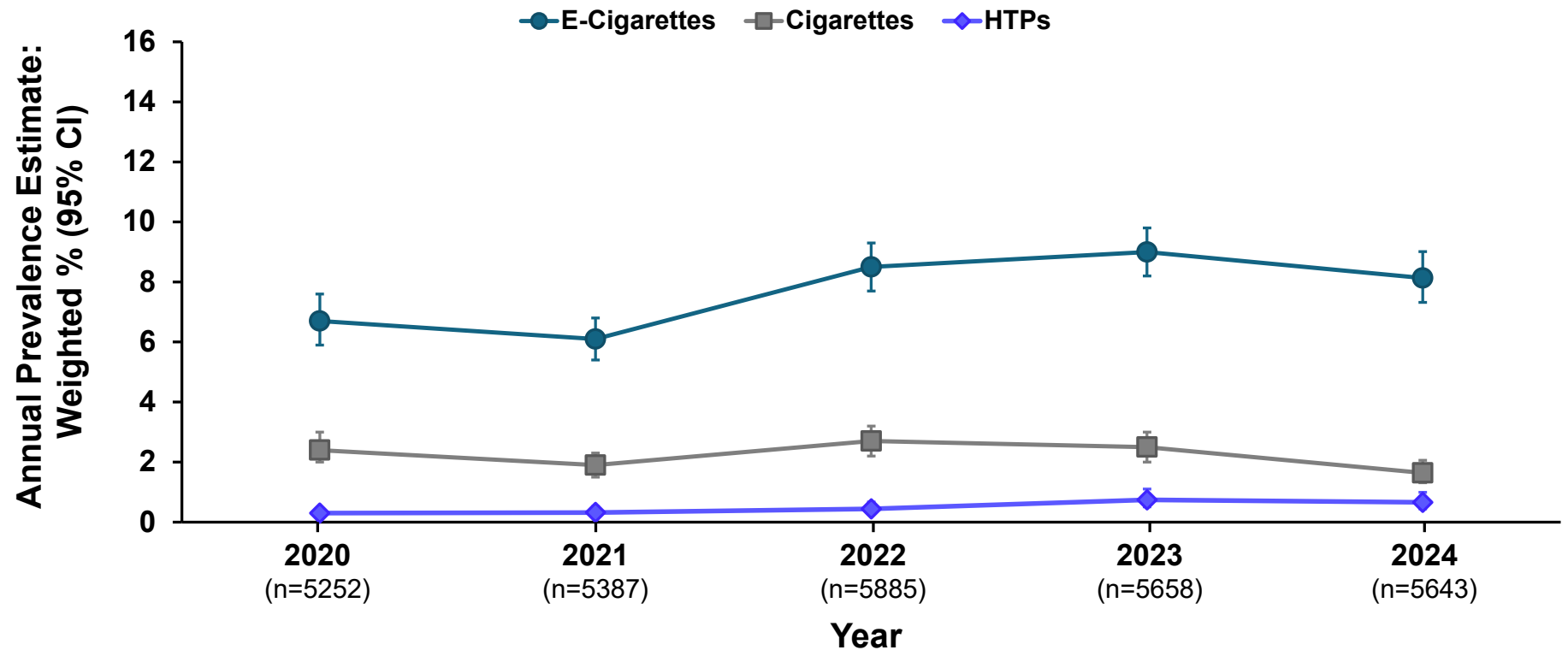
Estimate:

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

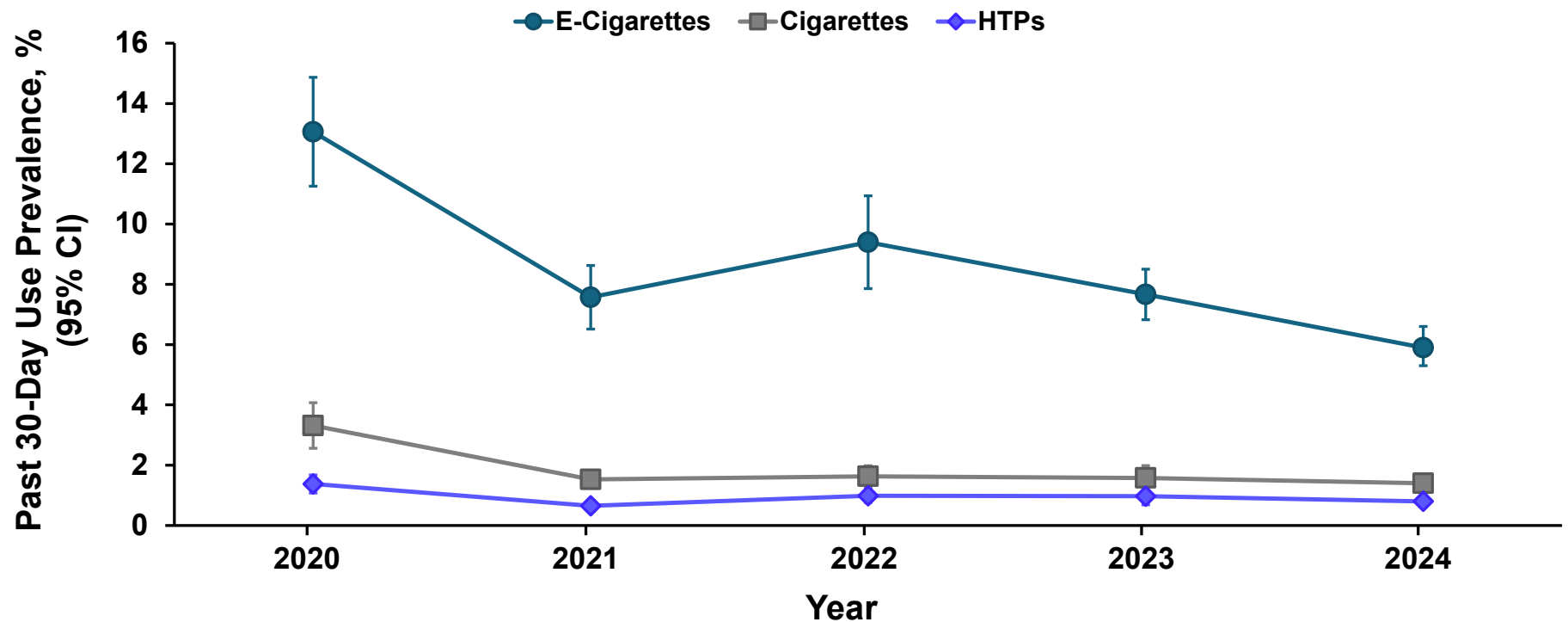
Past 30-Day Use of HTPs and Other TNPs



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

Past 30-Day Use of HTPs and Other TNPs



Sources: NYTS estimates calculated directly from public use data ([https://www.cdc.gov/tobacco/data\\_statistics/surveys/nyts/data/index.html](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**

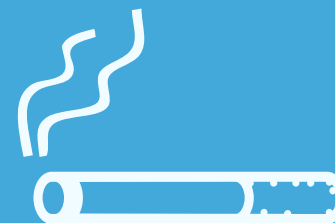
**Adults 21+**



**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 <b><u>NOT</u></b> advertise in publications for general circulation unless its audience is reasonably estimated to be at least 85% adults (21+)	
We do <b><u>NOT</u></b> engage via email/direct mail with any consumers who aren't confirmed to be 21+	
We do <b><u>NOT</u></b> have branded social media advertising accounts on platforms without age-restriction controls	
We do <b><u>NOT</u></b> pay social media influencers to endorse our products	

# Age-Verification at IQOS Point-of-Sale

## Face-to-Face



1



Face-to-face age check & **confirmation** of tobacco or nicotine product use

2



Age verification via independent age and identity **verification service(s)**

3



**Consumer receives product**

## E-Commerce



1



**Notification** of age-check & confirmation of tobacco or nicotine product use

2



**One-Time-Password** via mobile number

3



Age verification via independent age and identity **verification service(s)**

4



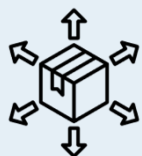
**Access to e-commerce**

5



Identity and age verification **upon delivery**

# Use of Reduced Exposure Claim



**Device  
packaging**  
*IQOS 3.0*



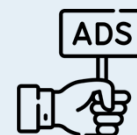
**Digital Property**  
Brand website



**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

**WARNING: This product contains nicotine. Nicotine is an addictive chemical.**

Discover the science behind IQOS.

Find out why 100 million users in over 70 countries use IQOS.



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.

**Why heating is better.**

IQOS combines science and technology to offer a new alternative to smoking. IQOS uses precision HEATSTONED™ TECHNOLOGY to heat tobacco slowly just enough to release nicotine and tar without burning the tobacco. That means no fire, no ash, and less smell than cigarettes.

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.

[DISCOVER MORE](#)

## PRODUCT TRIAL In-Store Brochure

**WARNING: This product contains nicotine. Nicotine is an addictive chemical.**

**Good to know:**

- There are 10.8 million IQOS users worldwide\* as of October 2024.
- 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.

**SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.**

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

- 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

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## Collective Evidence Supports MRTP Renewal

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



# Collective Evidence Supports MRTP Renewal

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



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

