Computational Modeling for Assessing Population Impact (COMPUTE)

Population Health Impact Assessment of a New Oral Nicotine Pouch Product

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Center for Research and Technology

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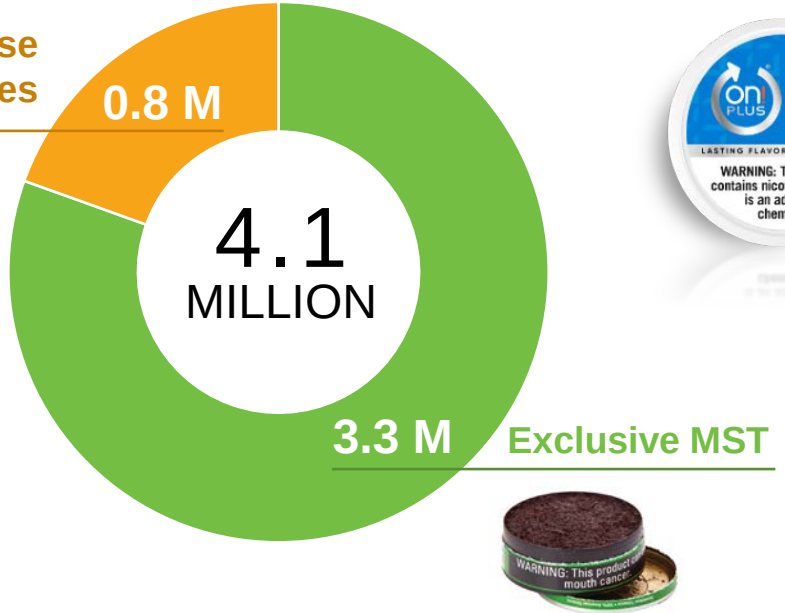
Agenda

- Case Study: on! Plus™ Nicotine Pouches
- Scientific Framework
- Population Modeling Framework
- Model Inputs and Data Sources
- Sensitivity Analyses
- Conclusions

Case Study: on! Plus™ Nicotine Pouches



Based on Adult Tobacco Consumer Tracker 2024, Data; MST=moist smokeless tobacco.

Scientific Framework

NET BENEFIT TO THE POPULATION

Constituent Reduction

Product Design and Control

Chemical and Physical Characterization

THE PRODUCT

- Chemistry Manufacturing and Controls
- Product Stability
- Chemical Characterization

Individual Risk Reduction

Toxicology and Risk Assessment

Studies in Adult Human Subjects

EXPOSURE and HEALTH RISK

- Toxicology and Risk Assessment
- Health Risk Assessment (absolute and relative)
- Human Studies
- Human Factors Assessment

Population Harm Reduction

Perception and Behavior Assessment

Risks and Benefits to Health of the Population

IMPACT on the POPULATION

- Risk Perceptions (absolute and relative)
- Impact of Product on Users
- Impact on Non-users
- Overall Impact on the Population
- Environmental Assessment

Population Modeling

NET BENEFIT TO THE POPULATION

Risk
of using the new tobacco product relative to smoking

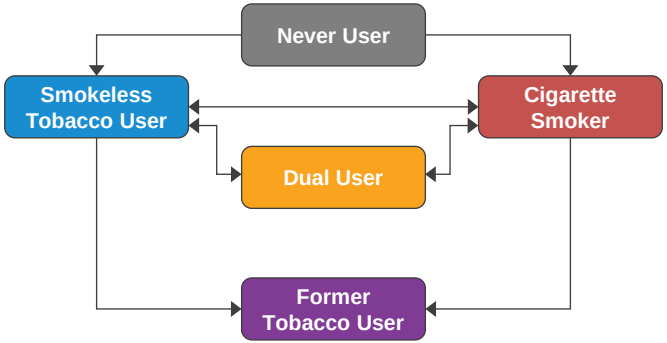
Benefit/Risk

Changes
in product use patterns due to the introduction of the product

Modeling Framework

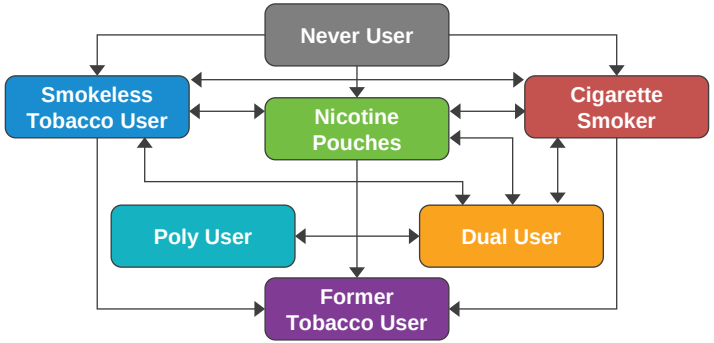
BASE CASE
Cigarettes and Smokeless Tobacco

Simulation Period: 2000-2100



MODIFIED CASE
Introduction of *on! Plus*™ into the Market

Introduction of *on! Plus*™ in 2025



The impact on the population as a whole is determined based on the difference in tobacco use prevalence and all-cause mortality (premature deaths prevented) between the Base and Modified Case scenarios

Source: Hannel, T; Wei, L; He, Y; Muhammad-Kah, R; Largo, E; Sarkar, M. "Modeling the Population Health Impact of Flavor Variety and Potential Risk of Youth Initiation Resulting from the Marketing of an Oral Nicotine Pouch Product". Poster presented at the 77th Tobacco Science Research Conference (TSRC), September 8-11, 2024.
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Agenda

Case Study: on! Plus™ Nicotine Pouches

Scientific Framework

Population Modeling Framework

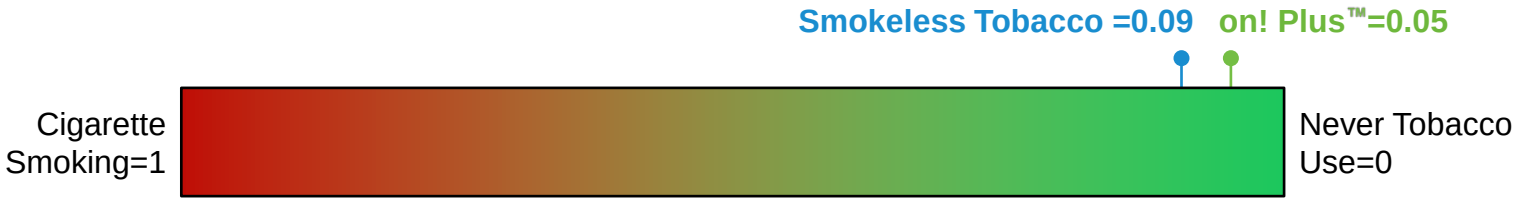
Model Inputs and Data Sources

Sensitivity Analyses

Conclusions

Mortality Risk Relative to Smoking

Excess Relative Risk (ERR) Compared to Smoking



Dual Use was set the same as exclusive cigarette smoking

Published all-cause mortality risk for **ST**

ERR=0.09[1]

Multi-criteria decision analysis approach

ERR=0.02[2]

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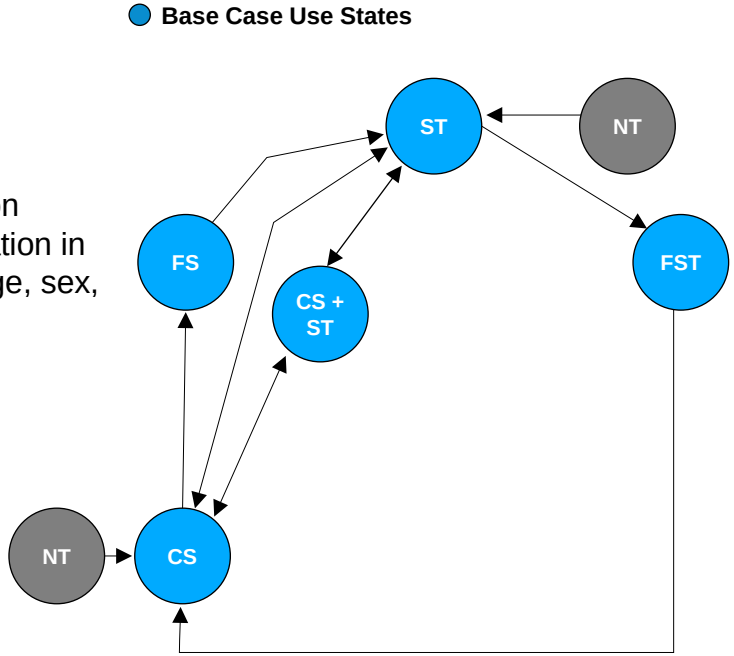
1. Fisher, MT; Tan-Torres, SM; Gaworski, CL; Black, RA; Sarkar, M. Smokeless tobacco mortality risks: An analysis of two contemporary nationally representative longitudinal mortality studies. *Harm Reduct J.* 2019;16:27.
2. Nutt, et al. Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. *Eur Addict Res.* 2014;20:218-225.

Transition Model

BASE CASE MODEL
is initialized with a population reflective of the U.S. population in the year 2000 in terms of age, sex, smoking and ST use status

DATA SOURCES: Cancer Intervention and Surveillance Network (CISNET)[1]
Population Assessment of Tobacco and Health (PATH)
Published Literature[2&3]



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1. Jeon, J., Holford, T. R., Levy, D. T., Feuer, E. J., Cao, P., Tam, J., . . . Meza, R. (2018). Smoking and Lung Cancer Mortality in the United States From 2015 to 2065: A Comparative Modeling Approach. *Annals of internal medicine*, 169(10), 684-693. doi:10.7326/M18-1250
2. Zhu, S., Wang, J. B., Hartman, A., Zhuang, Y., Gamst, A., Gibson, J. T., . . . Galanti, M. R. (2009). *Quitting cigarettes completely or switching to smokeless tobacco: Do US data replicate the Swedish?*
3. Chang, J. T., Levy, D. T., & Meza, R. (2017). Examining the Transitions Between Cigarette and Smokeless Tobacco Product Use in the United States Using the 2002–2003 and 2010–2011 Longitudinal Cohorts. *Nicotine & Tobacco Research*, 20(11), 1412-1416. doi:10.1093/ntr/ntx251

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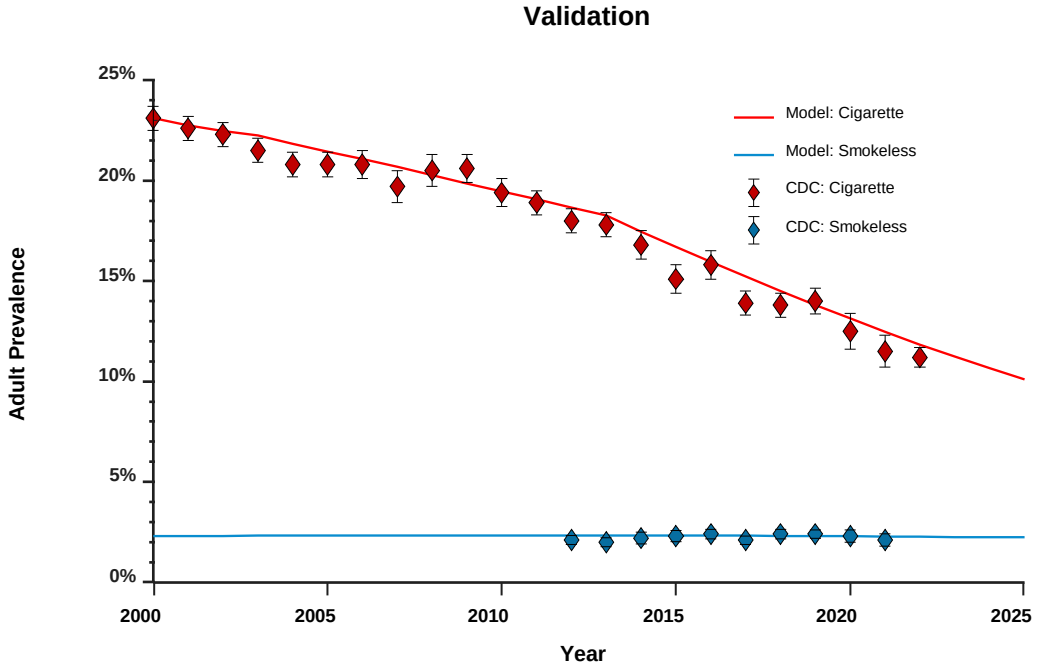

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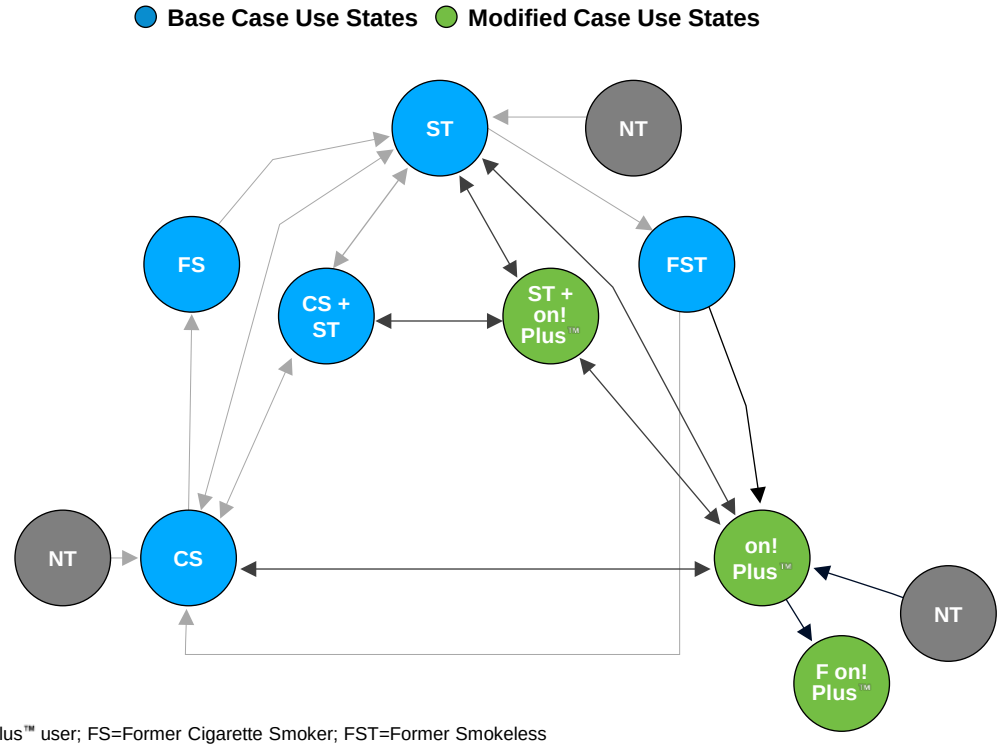

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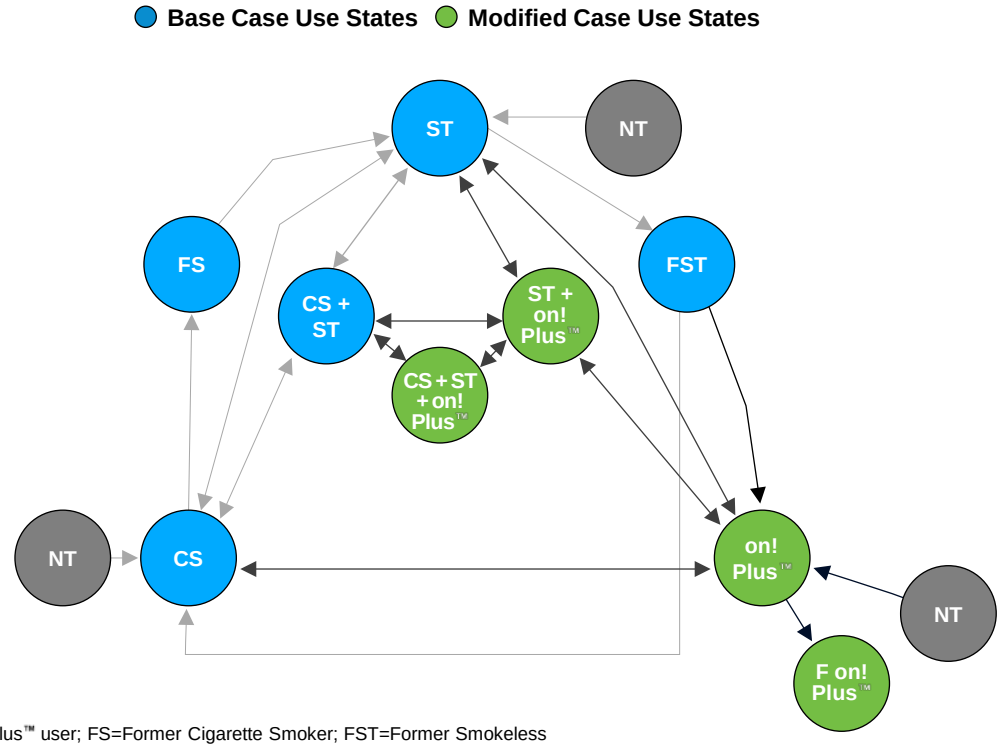

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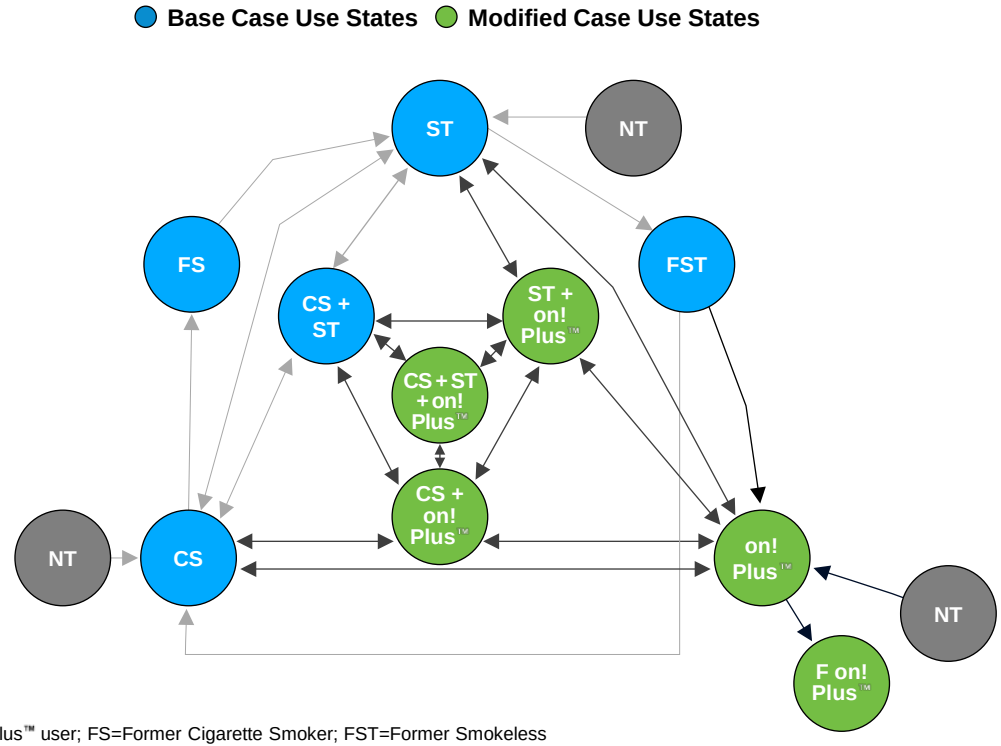

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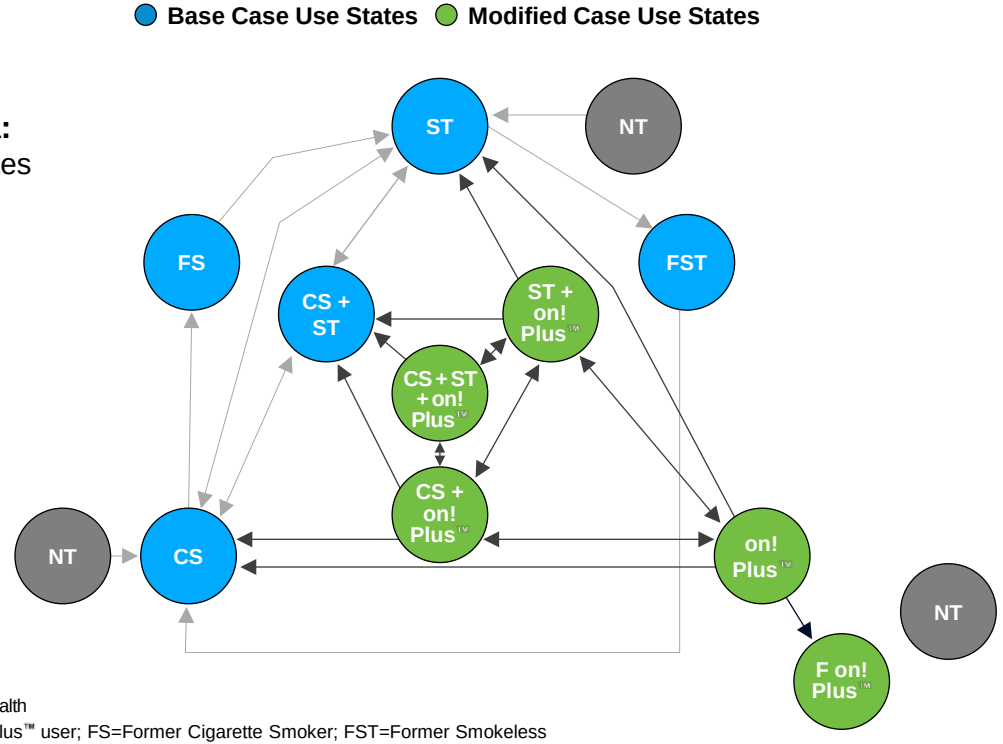

DATA SOURCES

National Longitudinal Data:

⟶ **PATH:** Snus transition rates

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Transition Model

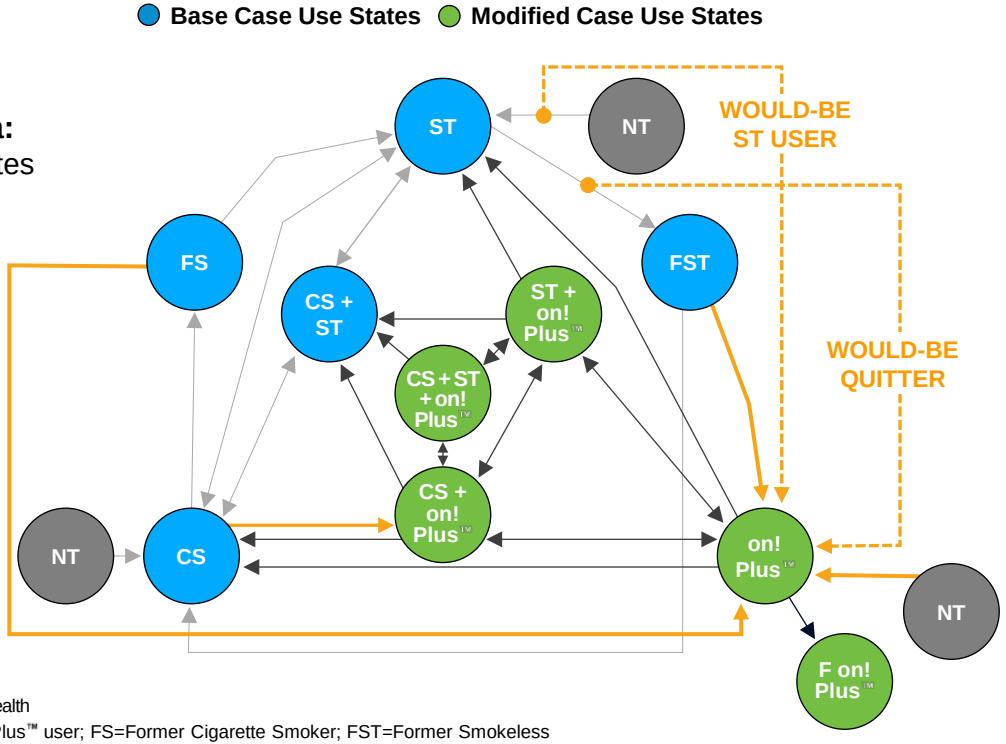
DATA SOURCES

National Longitudinal Data:

→ **PATH:** Snus transition rates

Product-Specific Studies:

→ **Perception and Behavioral Intentions Study:** Basis for nonuser transition estimates



WOULD-BE ST USER: Hypothetical proportion of never users that would have initiated ST but instead initiate on! Plus™ use

WOULD-BE QUITTER: Hypothetical proportion of ST users that would have quit but instead transition to on! Plus™

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Transition Model

DATA SOURCES

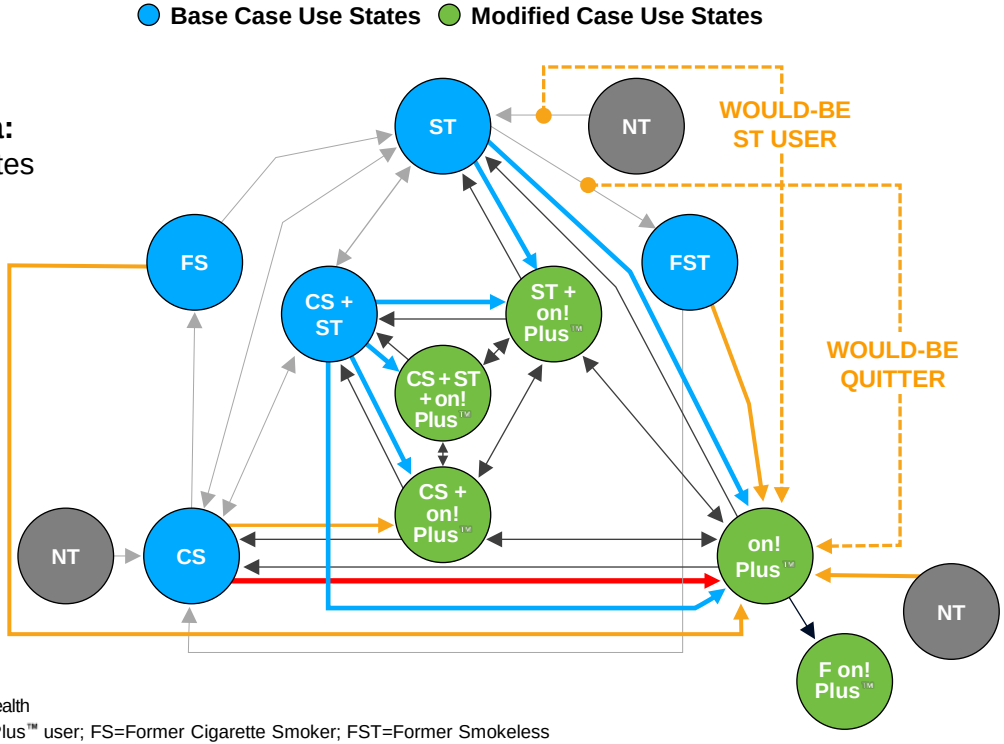
National Longitudinal Data:

→ **PATH:** Snus transition rates

Product-Specific Studies:

→ **Perception and Behavioral Intentions Study:** Basis for nonuser transition estimates

→ **Actual Use Study:** Behavioral transition rates estimated from 6-weeks of use



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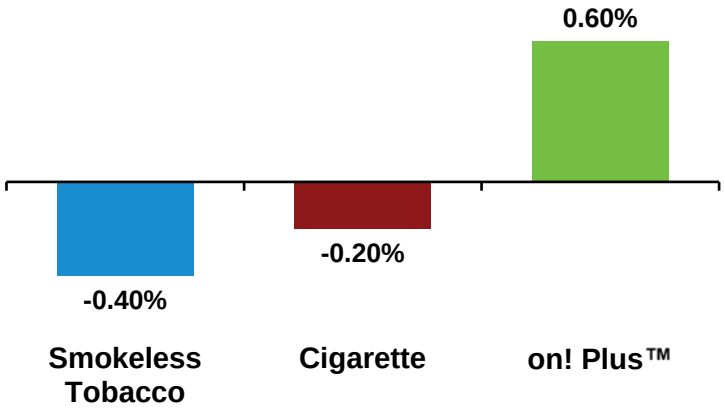
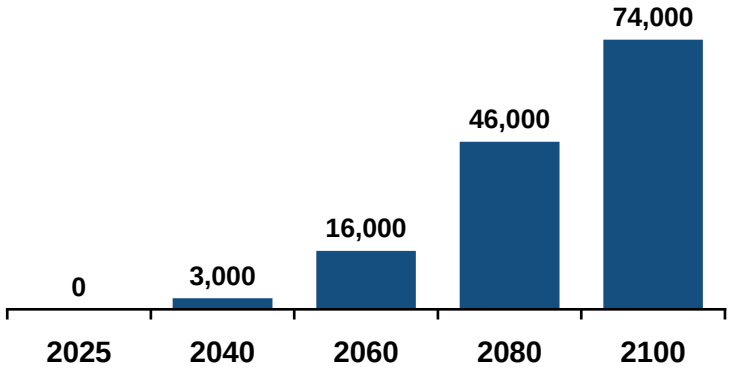
Impact on the Population as a Whole

NET BENEFIT TO THE POPULATION

Adult Prevalence Percentage Point Change



Premature Deaths Prevented



Modeling Predicts

REDUCTION in ST prevalence by 0.40%

PREVENTION of 74,000 premature deaths

→ Achieved over 75 years with the introduction of on! Plus™ in the Market

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Case Study: on! Plus™ Nicotine Pouches

Scientific Framework

Population Modeling Framework

Model Inputs and Data Sources

Sensitivity Analyses

Conclusions

NET BENEFIT TO THE POPULATION

Sensitivity analyses are used to evaluate the impact of various input parameters on the model outcome measures

Allows for the evaluation of questions **related to specific regulatory concerns:**

FLAVORS

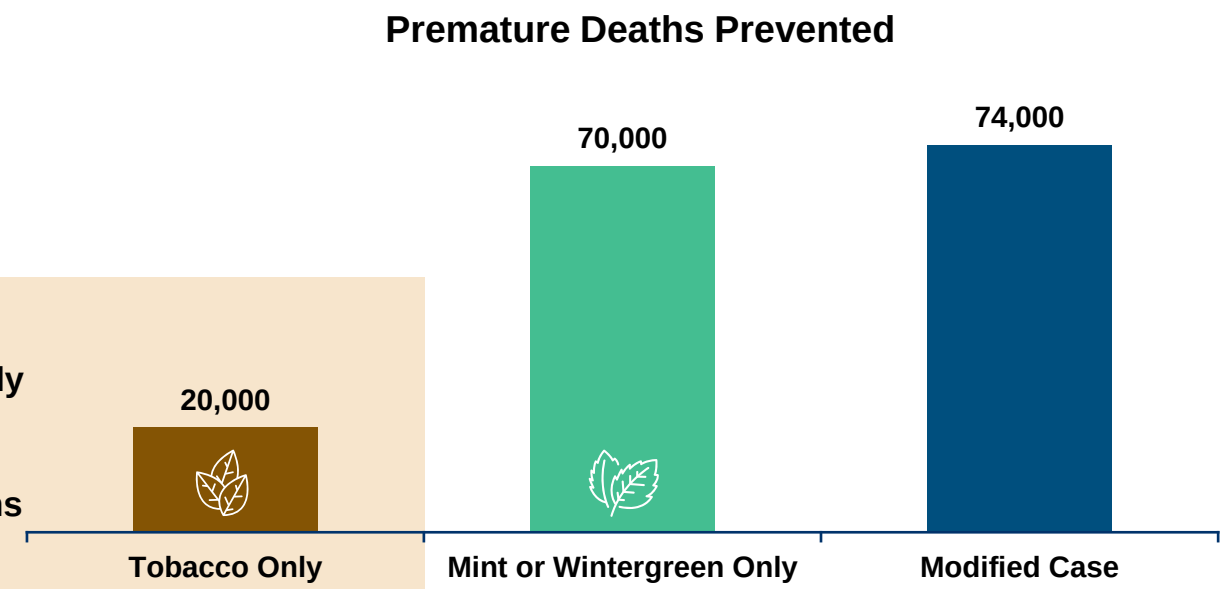
How might switching associated with flavor appeal impact the model's outcomes?

YOUTH INITIATION

What level of youth initiation would result in a risk to the population?

Sensitivity: Impact of Flavors

Limiting the on! Plus™ portfolio to tobacco only flavor reduces the population benefit to 20,000 premature deaths prevented



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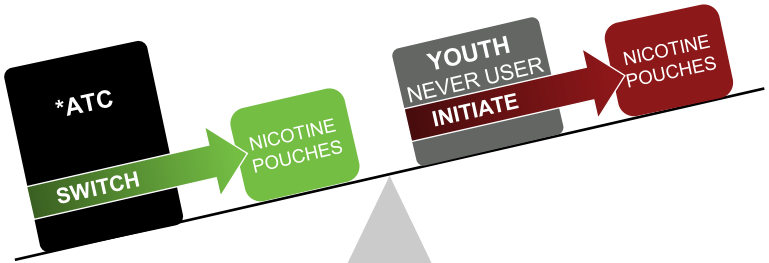
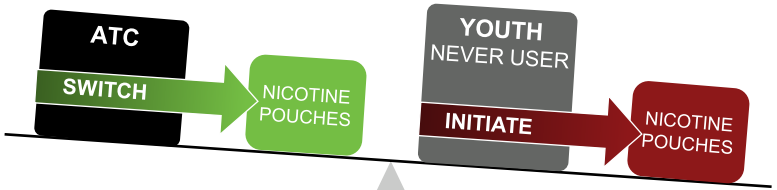
Tipping Point Sensitivity Analyses

Public Health
BENEFIT



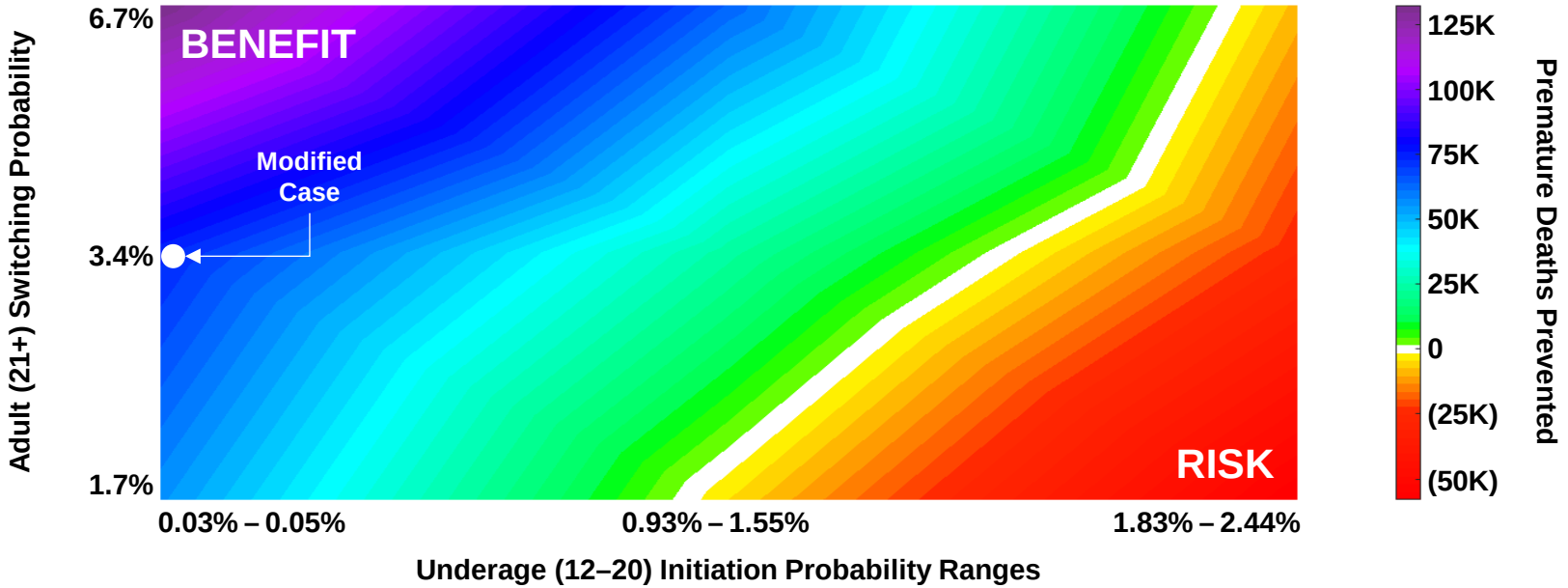
Public Health
RISK



Tipping point can be used to evaluate the
risk of initiation versus the benefit from ATC switching

*Adult Tobacco Consumer

Sensitivity: Impact of Concurrently Varying Initiation and Switching Rates



All other transitions held constant.

Conclusion

Modeling indicates marketing of on! Plus™ will have a positive population health benefit

Modeling allows estimation of the number of **premature deaths prevented** and **reduction in prevalence**

Sensitivity analyses demonstrate the need for product flavor variety

Tipping point sensitivity analyses demonstrate low risk to underage populations