

Snus Smokeless Tobacco Products

Michael T. Fisher, PhD

Outline



- PM USA's Business Proposition
- Product Design
- Product Assessment

Background

- Some adult smokers are interested in smokeless tobacco alternatives to smoking
- Today's alternatives, chewing, dipping and spitting tobacco appeal to some adult smokers
- Many adult smokers do not find these to be acceptable alternatives
 - Spitting
 - Taste
 - Image

Taboka



- A new brand
- A new product
- A new category for PM USA
- Indianapolis, IN
July, 2006

Marlboro Snus



- Learning from Taboka
- Built on the Marlboro brand
- Dallas/Fort Worth, TX
August, 2007

How Our Snus Products Differ from Moist Smokeless Tobacco (MST)



Our Snus
Products

MST

Spit	No	Yes
Portion size	0.23 grams	~1.5 grams
Form	Pouch	Primarily Loose
Tobacco Processing	Pasteurized	Fermented
Flavor Film Technology	Yes	No
Moisture	12%	~50%

The Pouch

Each pouch contains pasteurized tobacco, fiber, water, flavors, and other ingredients



Product Design

- Tobaccos are selected:
 - based on lower levels of TSNAs
 - to meet adult smokers' preferences

Approach to Toxicological Acceptability Assessment



- Based on food and consumer products evaluation model
 - Initial verification of acceptability of individual design parameters & characteristics (e.g., ingredients, processes, & materials)
 - Subsequent products use design parameters & characteristics previously determined to be acceptable

Toxicological Acceptability Evaluation



- Assessment of pouch material and added ingredients
 - pouch material - FDA approved for food contact
 - other non-tobacco added ingredients - FDA approved for food use
- Assessment of our product design
 - assessment parameters within the range of commercially available smokeless tobacco products in the U.S and Sweden.

Selection of Assessment Elements



- Chemical constituents
 - selected based on those:
 - listed in the Gothiatek Standard* and;
 - identified in authoritative reports
 - IARC, U.S. Surgeon General, WHO, NCI
- Biological tests
 - selected based on PM USA product assessment guidelines
- Microbiological tests
 - selected based on consultation with experts in food microbiology

*www.gothiatek.com

Reference Market Products

Loose

- Ettan Loose Snus
- Grovsnus Loose Snus
- Skruf Original Loose Snus
- Copenhagen Fine Cut
- Copenhagen Long Cut
- Skoal Fine Cut Wintergreen
- Skoal Long Cut Wintergreen
- Skoal Long Cut Mint
- Skoal Long Cut Cherry
- Red Seal fine cut
- Kodiak Regular Wintergreen
- Grizzly Fine Cut Natural
- Grizzly Long Cut Straight
- Timber Wolf Long Cut Wintergreen
- Cougar Long Cut Natural
- Husky fine cut

Portion pack

- Ettan Portion
- General White Portion
- General Original Portion
- Catch White Portion Licorice
- Catch White Portion Eucalyptus
- Catch Original Portion Licorice
- Mocca Anis Vit Mini portion
- Mocca Mint Vit Mini portion
- Metropol Vita Portions
- Skoal Bandits Wintergreen

Swedish snus
US products

Toxicological Acceptability Testing



Product constituents

- Nicotine
- pH
- Moisture
- TSNA's
 - NNN
 - NNK
 - NAB
 - NAT
- NDMA
- NPYR
- Nitrosoamino acids
- Metals / Elements
 - Cadmium
 - Lead
 - Arsenic
 - Nickel
 - Chromium
 - Selenium
 - Mercury
- B(a)P
- Aldehydes
 - Formaldehyde
 - Acetaldehyde
 - Acrolein
 - Crotonaldehyde

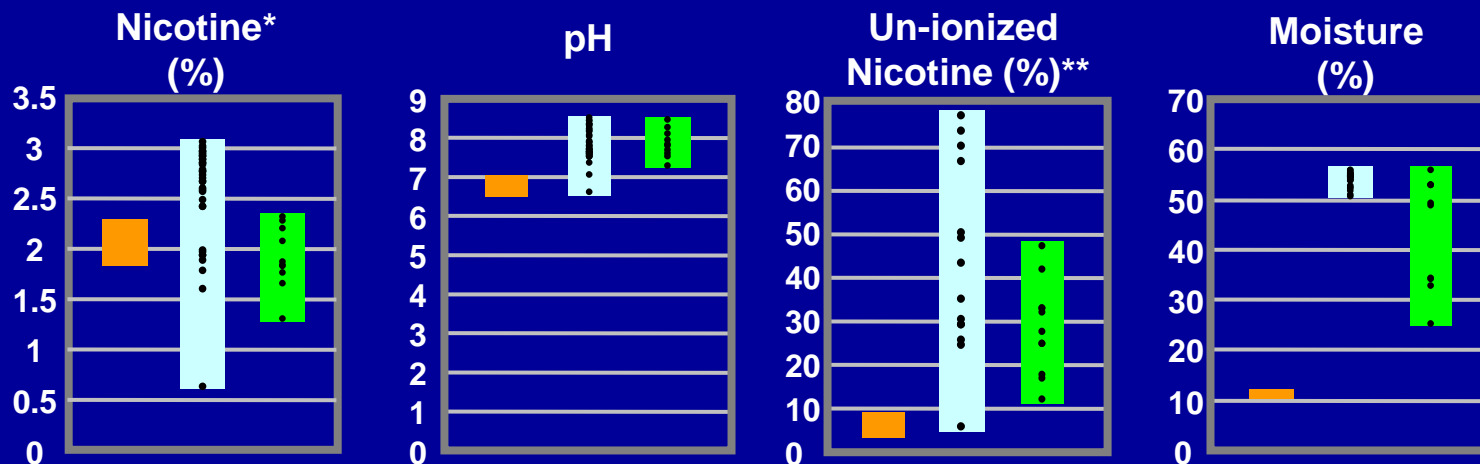
Biological activity

- Bacterial mutagenicity
 - Ames assay
- Cytotoxicity
 - neutral red uptake assay

Microbial activity

- Aerobic plate counts
- Mesophilic spore counts
- Pathogens
- Molds
- Yeasts

Analytical Parameters



Our snus products



Range of US smokeless tobacco products

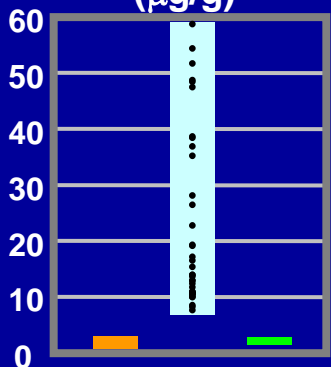


Range of Swedish snus products

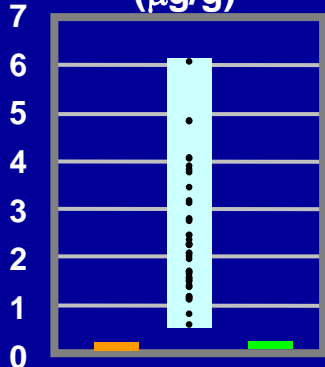
* dry weight basis
** 'as-is' weight basis

Analytical Parameters

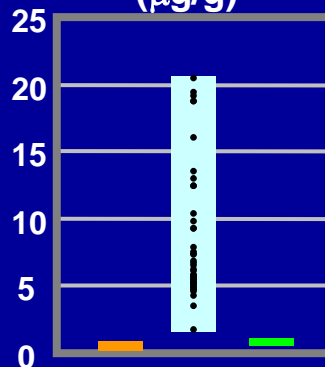
total TSNA
($\mu\text{g/g}$)



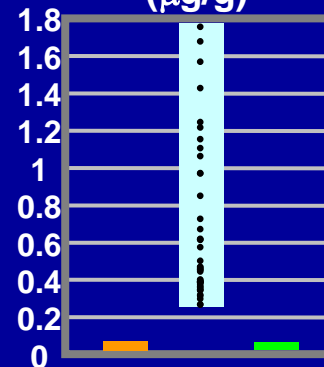
NNK
($\mu\text{g/g}$)



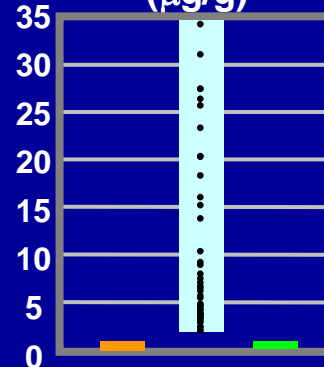
NNN
($\mu\text{g/g}$)



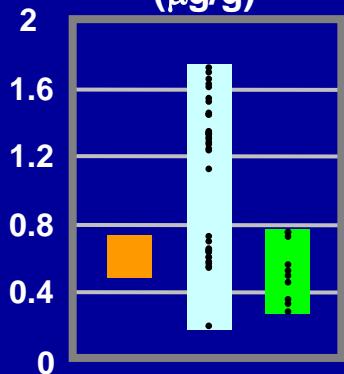
NAB
($\mu\text{g/g}$)



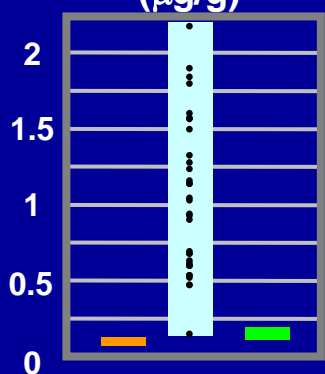
NAT
($\mu\text{g/g}$)



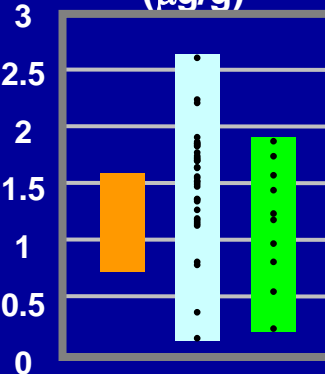
Cd
($\mu\text{g/g}$)



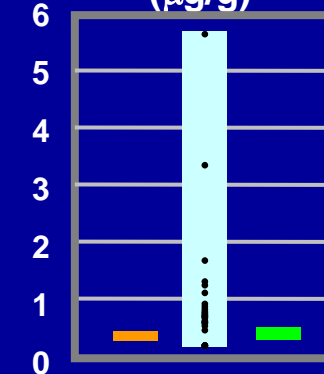
As
($\mu\text{g/g}$)



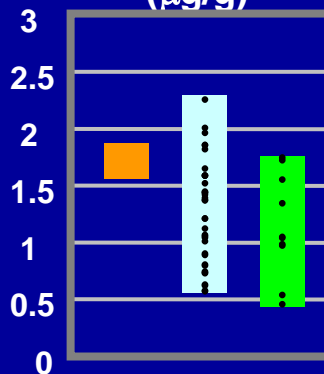
Ni
($\mu\text{g/g}$)



Pb
($\mu\text{g/g}$)



Cr
($\mu\text{g/g}$)



Our snus products



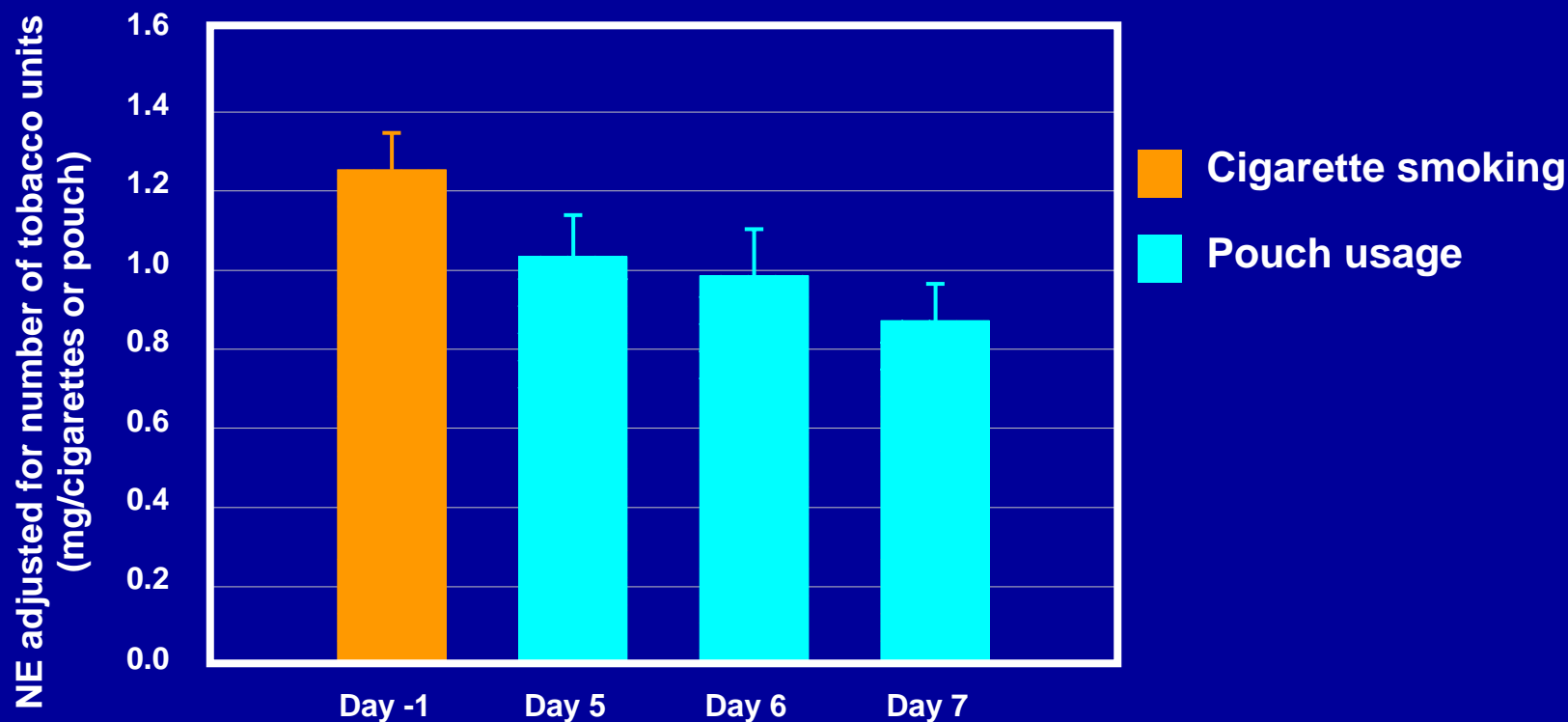
Range of US smokeless tobacco products

* dry weight basis



Range of Swedish snus products

Biological Assessment - Our Snus Products: Average Daily Urinary Excretion of Nicotine Equivalents*

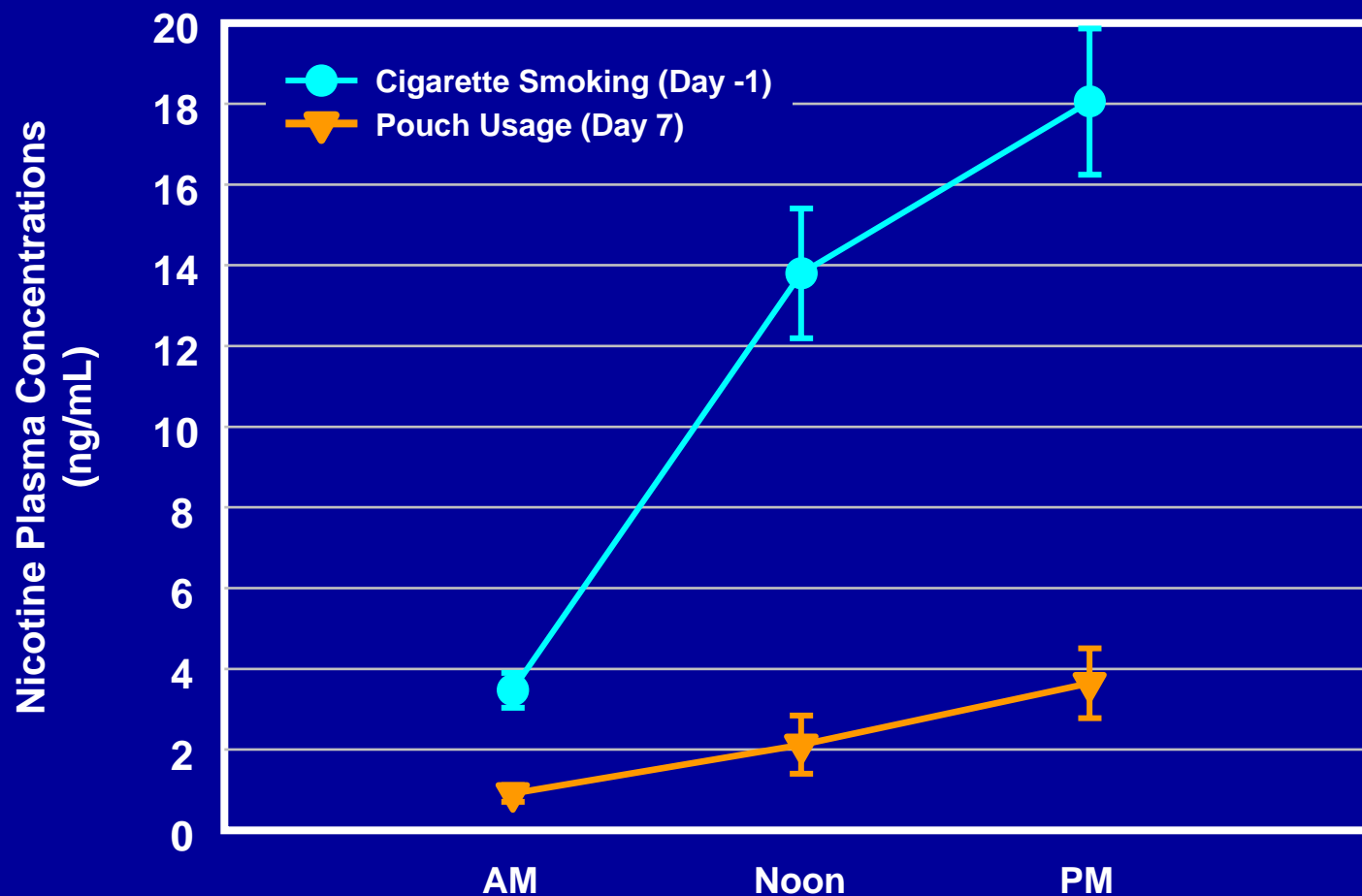


N = 26 subjects

Data shown as Mean \pm SE

*Nicotine equivalents (NE) - based on molar equivalents of nicotine calculated from daily urinary excretion of nicotine, nicotine glucuronide, cotinine, cotinine glucuronide, trans-3'-hydroxycotinine and trans-3'-hydroxycotinine glucuronide

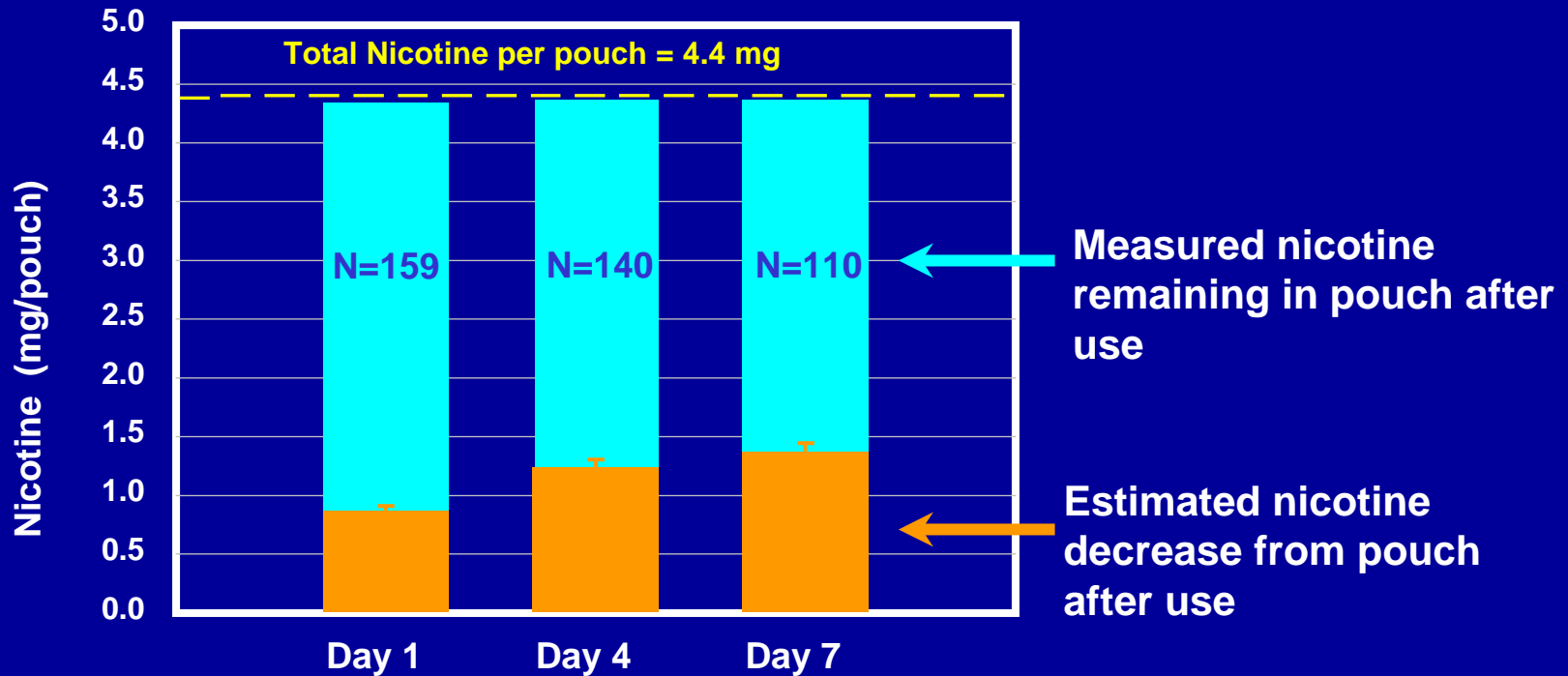
Biological Assessment – Our Snus Products: Nicotine Plasma Levels



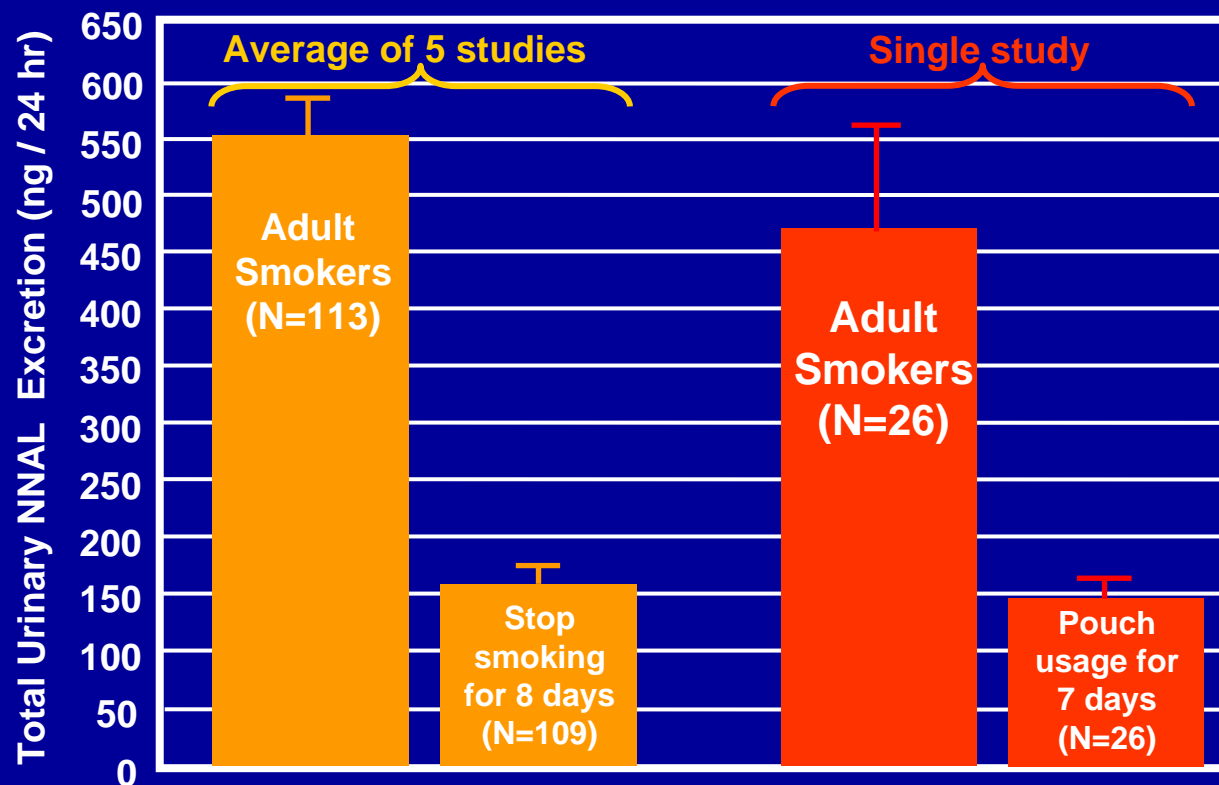
N = 26 subjects

Data shown as Mean \pm SE

Analytical Assessment - Our Snus Products: Nicotine Remaining in Pouch After Use



Biological Assessment - Our Snus Products: NNK



Data shown as Mean \pm SE

Summary

- **As part of our growth strategy, PM USA is test marketing spit-free tobacco pouch products made with pasteurized tobacco for adult smokers interested in smokeless tobacco alternatives.**
- **Our snus products have some similar design attributes to Swedish snus, designed especially for adult smokers in the U.S.**
- **Levels of toxicologically-relevant analytes assessed in our snus products are comparable to or lower than the reference set of commercially-available smokeless tobacco products.**
- **PM USA is not making any reduced exposure/risk/harm claims about our snus products.**