

Public Health Impact of Tobacco Product Innovation

Striking Out Against Tobacco

Little Rock Arkansas

September 2012

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Harvard School of Public Health

From: South Pomfret, VT



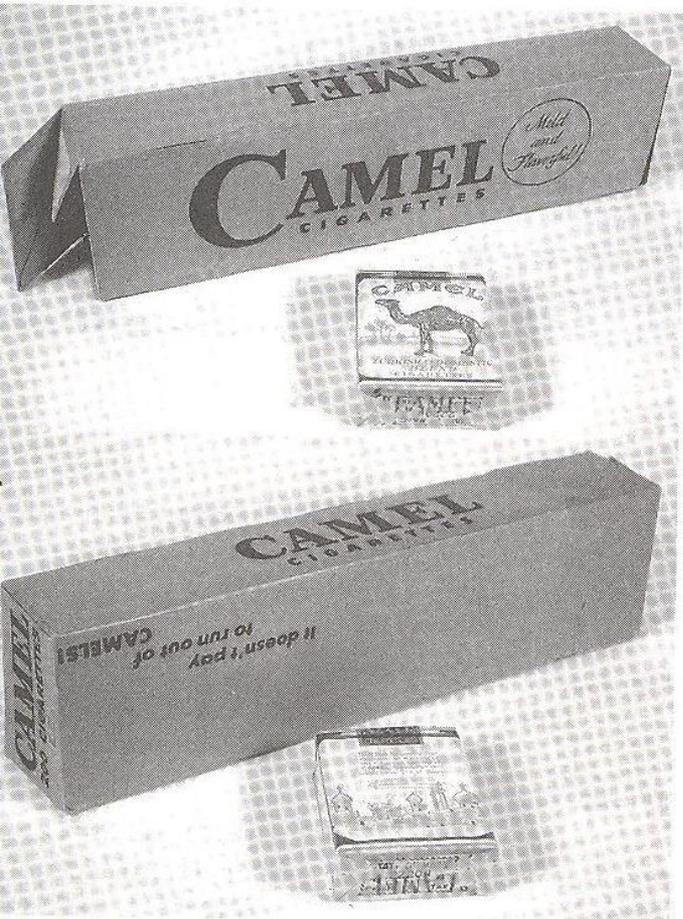
A typical day at work on tobacco control

Product Innovation

Tobacco Industry Strategies

- Initiation with Other Tobacco Products (flavored exempt from FDA) possibly leading to dual use?
- Continued Innovation of Conventional Cigarettes with avoidance of FDA Regulation
- Modified Risk Tobacco Products with industry driving approval based on political, public and litigation pressure. We have a “safer product” and government is not letting us protect.

The 20th Century vs the 21st The Total Tobacco Century



Camel - A Total Tobacco Brand



Leading Menthol Innovation

Capsule technology offers relevant consumer innovation

- Fresh menthol
- More choice for consumers
- Unique product point of difference



Innovation

- Breakthrough
 - Game-changing for the category



dissolvable
TOBACCO

©2008 R.J. REYNOLDS TOBACCO CO. (27)

3 Unique Ways to
Enjoy Tobacco
Anywhere, Anytime.

Place one in your mouth and enjoy.
Just let it dissolve away.
No spitting involved.



Innovation

- Incremental
 - Fresh and interesting, but not game-changing



Modern Smoke Free



The emergence of Modern Smoke Free Tobacco

2006-2008

Snus Learning



2006



Current

2009



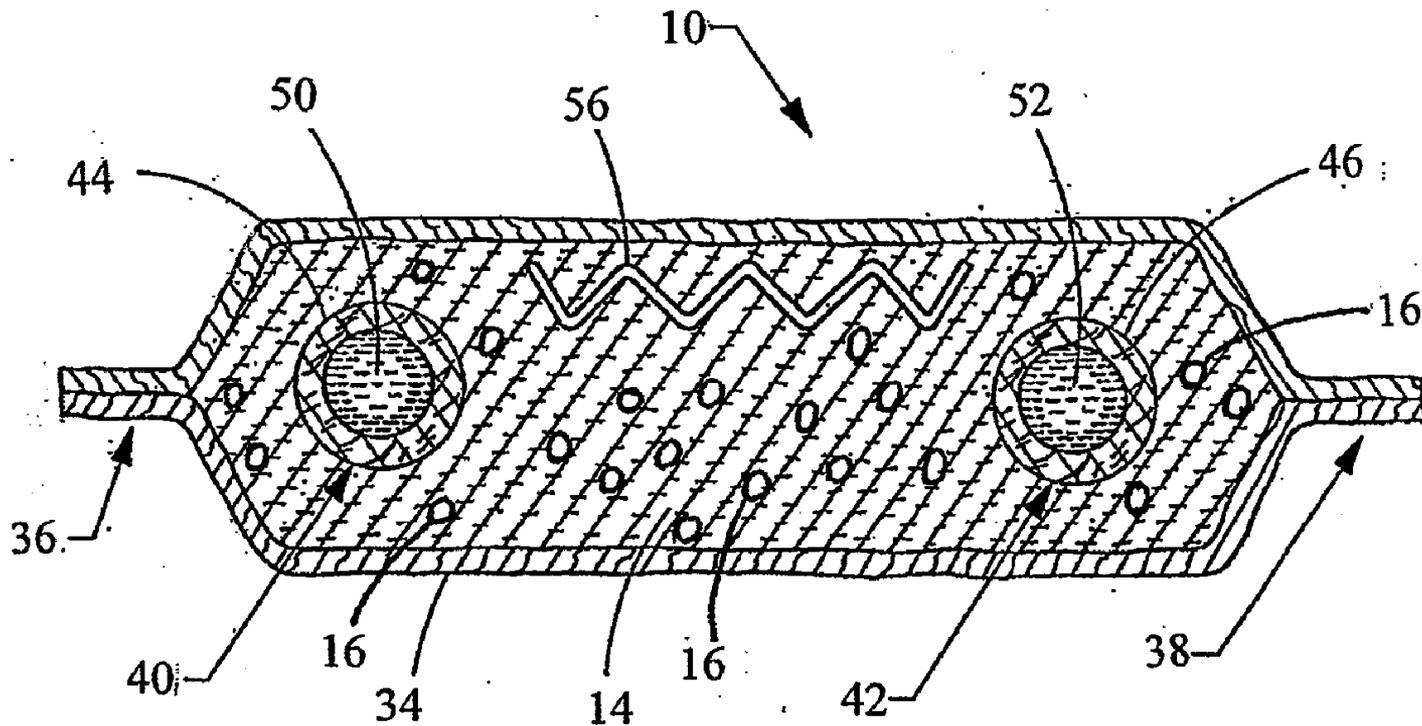
Camel Dissolvable Tobacco Products



(.6 – 3.3 mg/unit)

R.J. Reynolds Tobacco Company

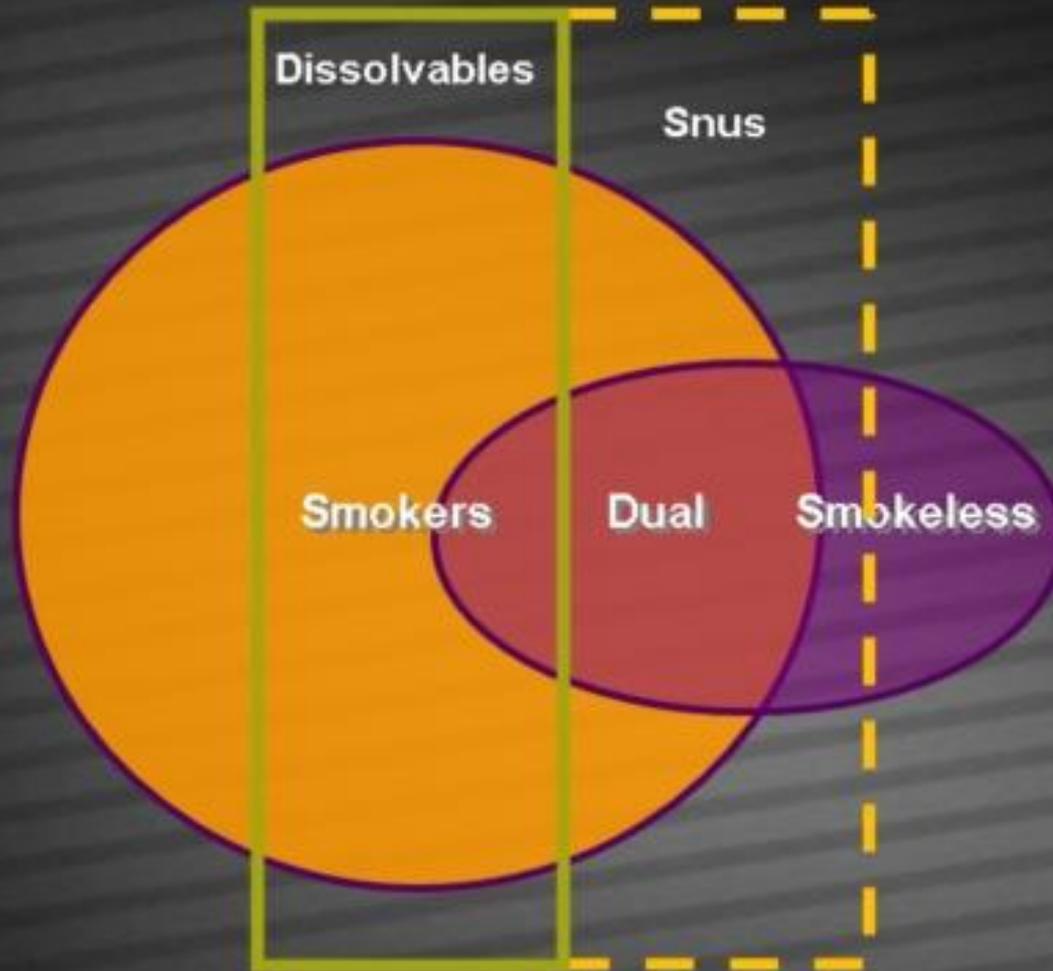
Smokeless Tobacco Product U.S. Patent (Feb. 7, 2008)



“The plurality of microcapsules...may include colorants, pH adjusters, fillers, disintegration aids, humectants, antioxidants and oral care ingredients...”

Total Tobacco Consumer Opportunity

AP





MEROKOK DAPAT MENYEBABKAN KANKER, SERANGAN JANTUNG, IMPOTENSI DAN GANGGUAN KEHAMILAN DAN JANIN

Targeted marketing of menthol: Young ethnic minorities and women



*Salem,
magazine ad
(Latina, Jane,
Cosmopolitan),
2004*

*Camel No. 9
Menthol,
introduced in
February 2007
and marketed to
women*



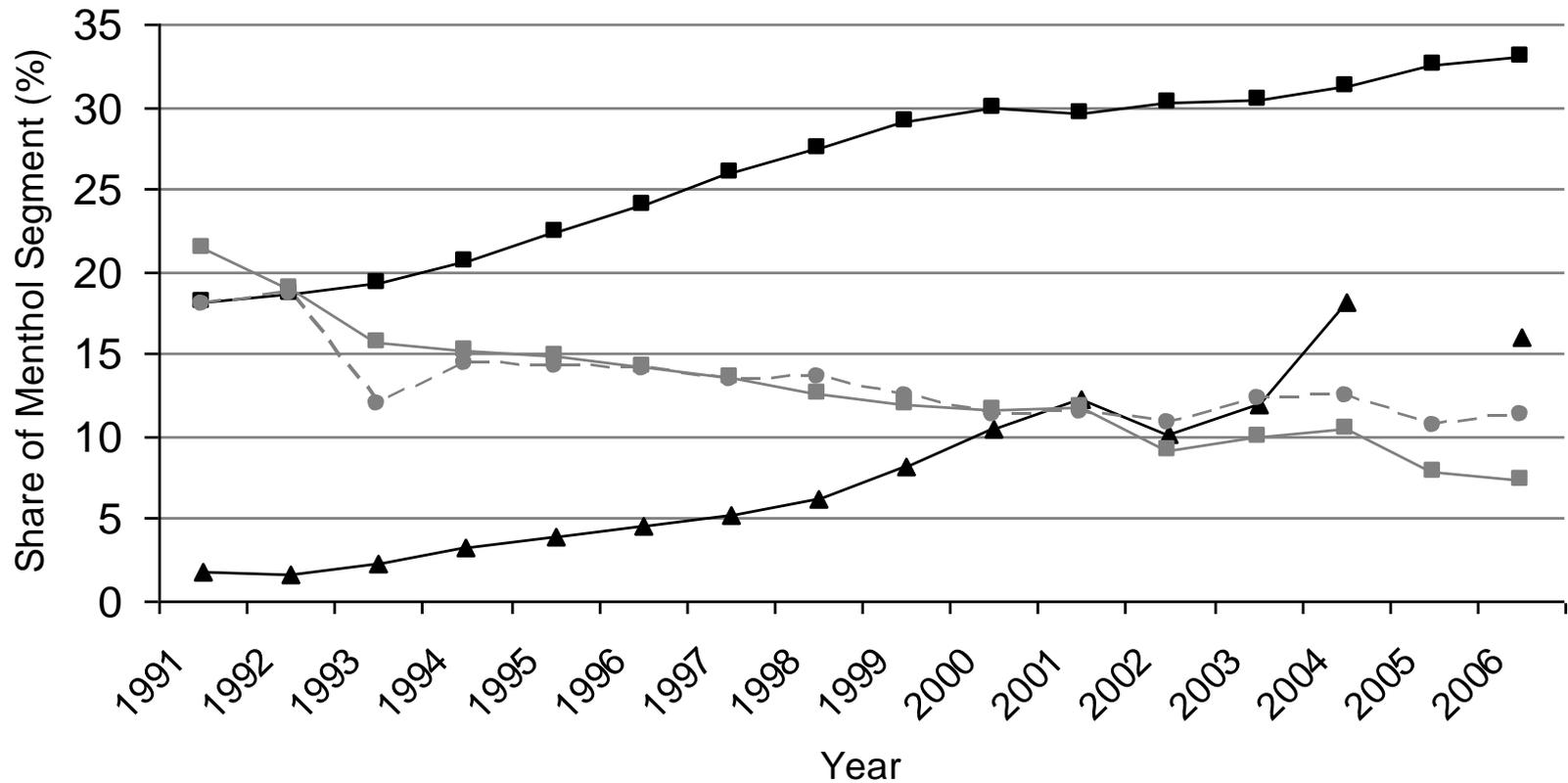
Salem hopes to reinvent itself by taking a brand whose current perception by the general public is a brand that is:

- ◆ Predominantly older (50+), female, suburban, light tasting highly mentholated product.

And changing that perception to:

- ◆ Current, modern, multicultural, dual male and female, smokers 21-34 years old, urban, relevant, balanced menthol taste.

Result: Market share of low-menthol brands steady and growing



Sources:
Maxwell Report;
Company
financial reports



Summary

- Great opportunity for Transformation through Innovation
- Growth and Innovation organization focuses vision and intensifies efforts
- Increases ability to develop substantial and breakthrough innovations
- Excited about potential for significant growth for RAI

Cigar Products that Could be Exempt from FDA Regulation Under H.R. 1639





S

FACTS



Skoal or Bust

The average cup size of a Skoal model is 36C.

Marlboro Architecture

Red



“Flavor
enjoyment”

Gold



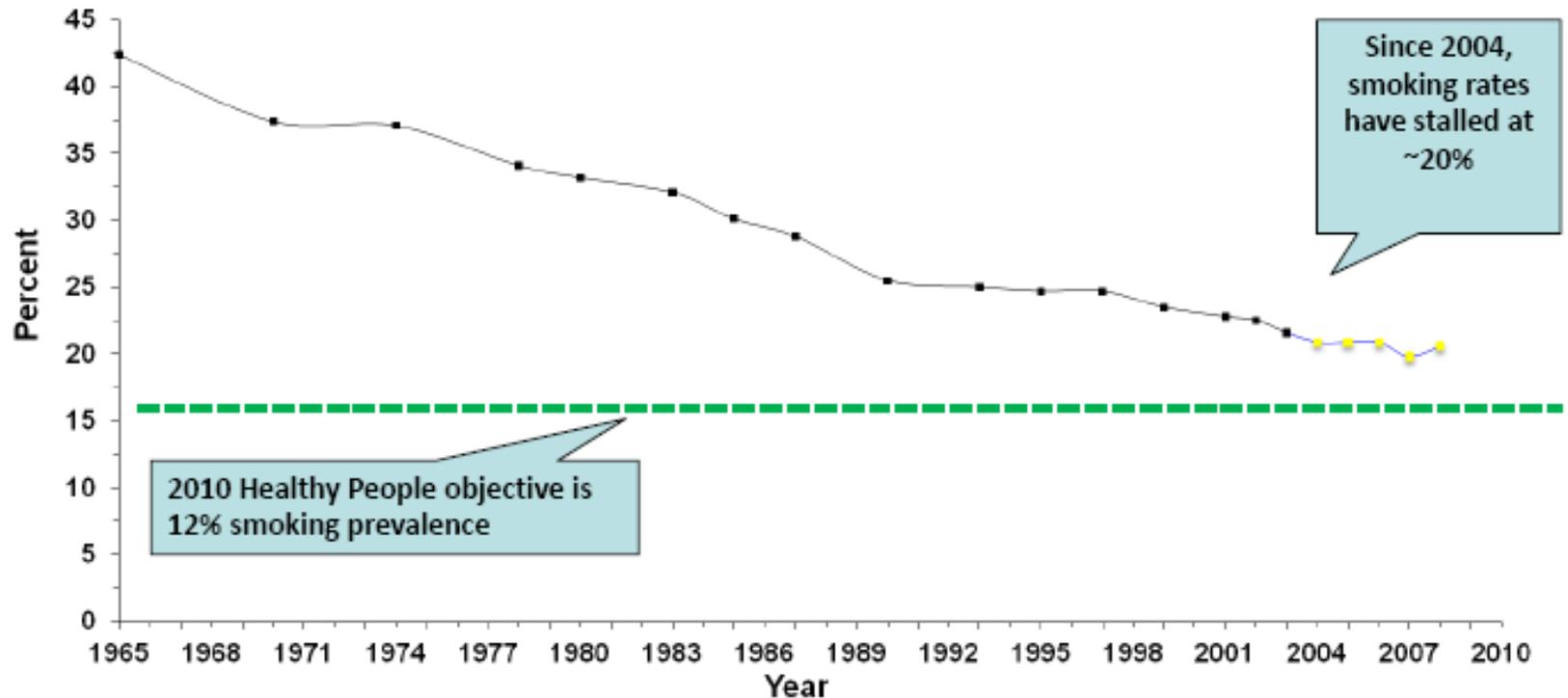
“Smooth taste
and style”

Fresh



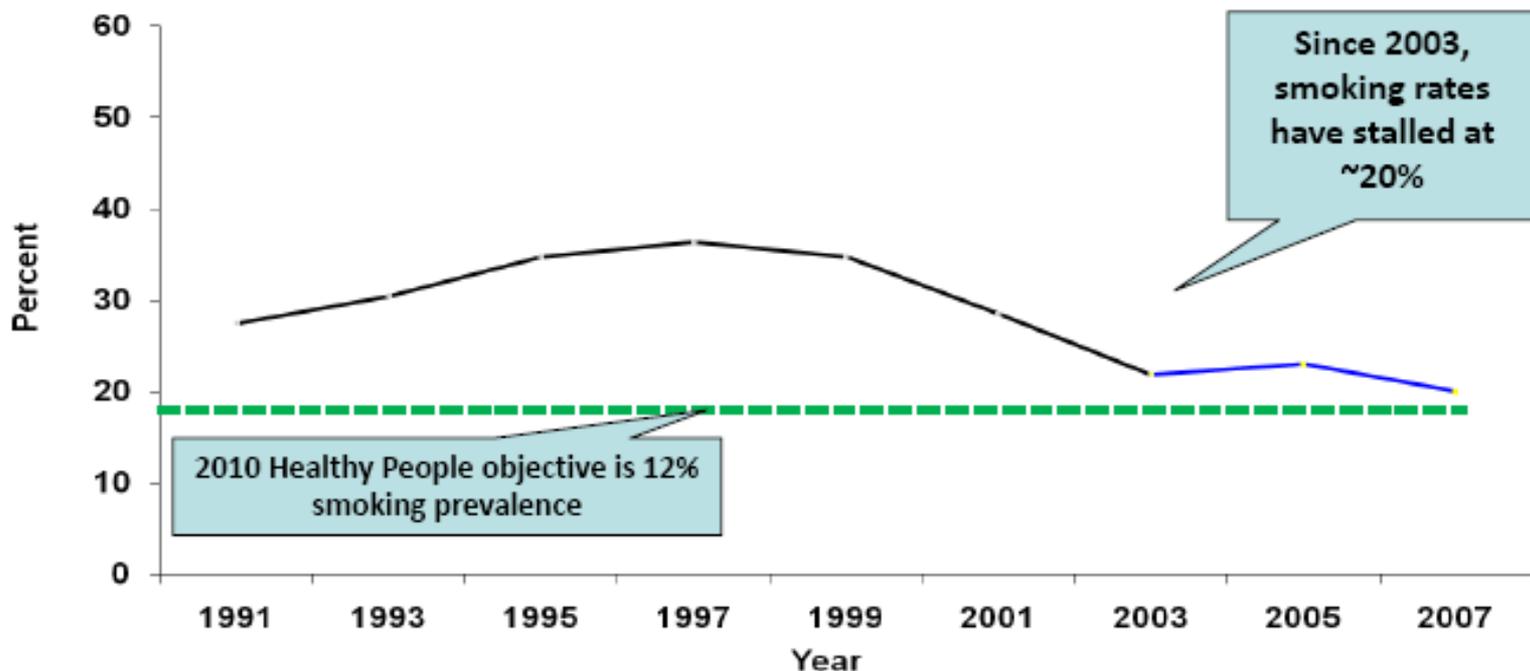
“Fresh taste
sensations”

After Decades of Progress, Decline in Adult Smoking Rates Has Stalled

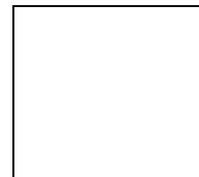


Adults who were current cigarette smokers, National Health Interview Surveys, 1965-2006.

Cigarette Smoking* Trends Among 9th-12th Graders, U.S., 1991-2007

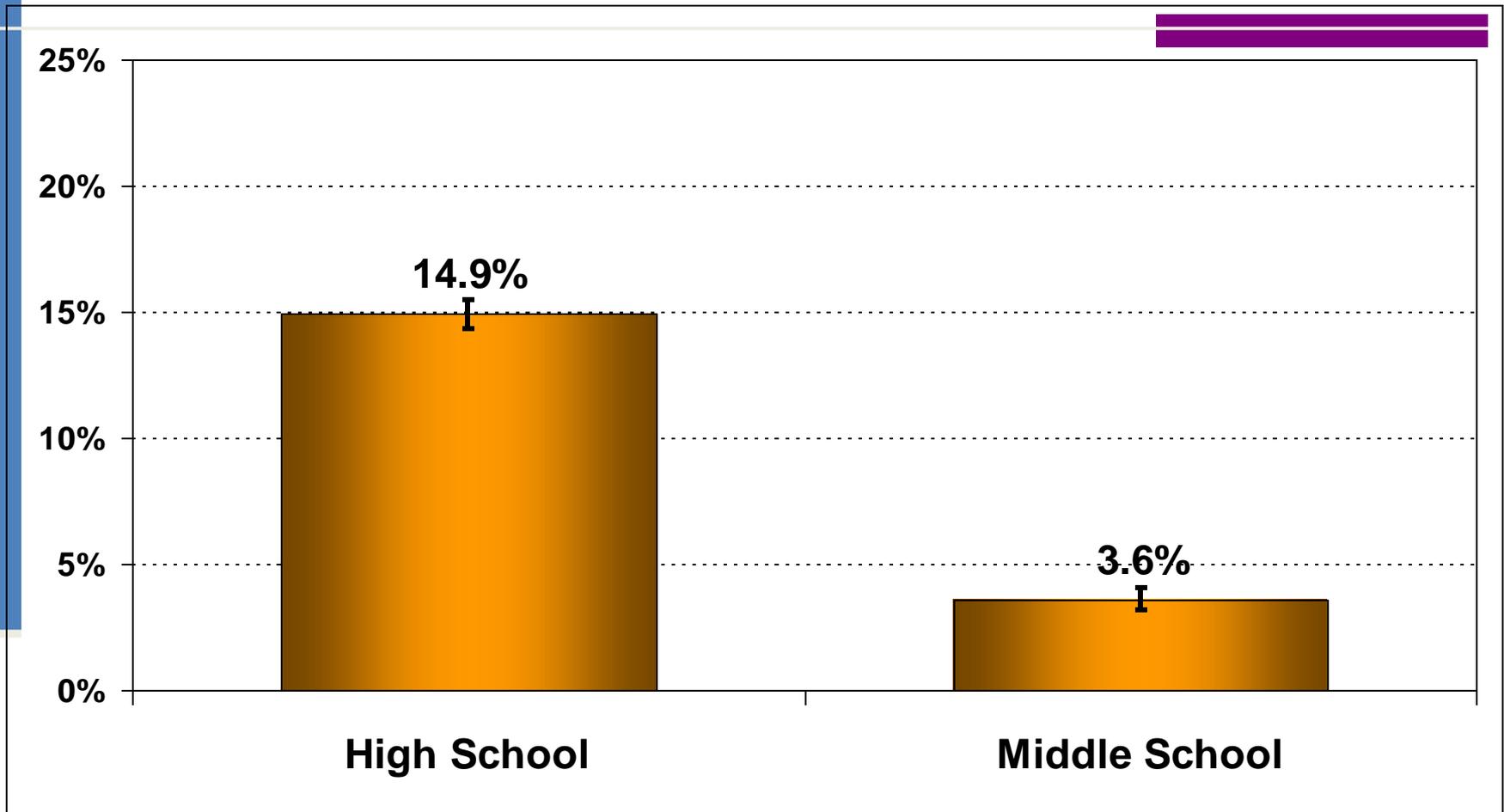


* Smoking on 1 or more of the previous 30 days.
Source: Youth Risk Behavior Surveillance Survey



Current Cigarette Smoking - 2010

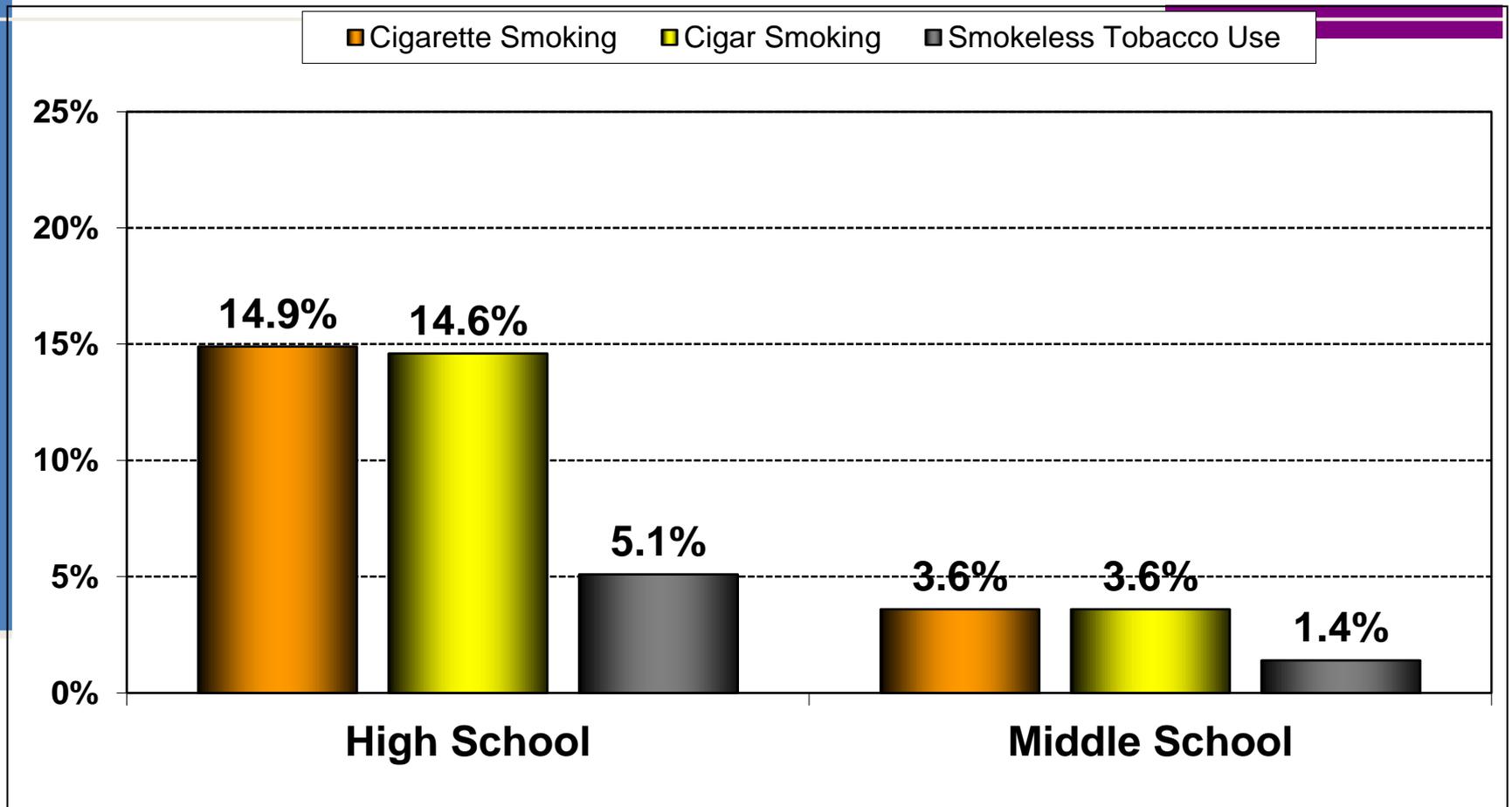
Maryland Public School Youth



Source: Maryland Department of Health and Mental Hygiene, Youth Tobacco Survey – Fall 2010. Current cigarette use is any cigarette smoking, even one or two puffs of a cigarette during the 30 days prior to the survey.

Current Use of Selected Tobacco Products - 2010

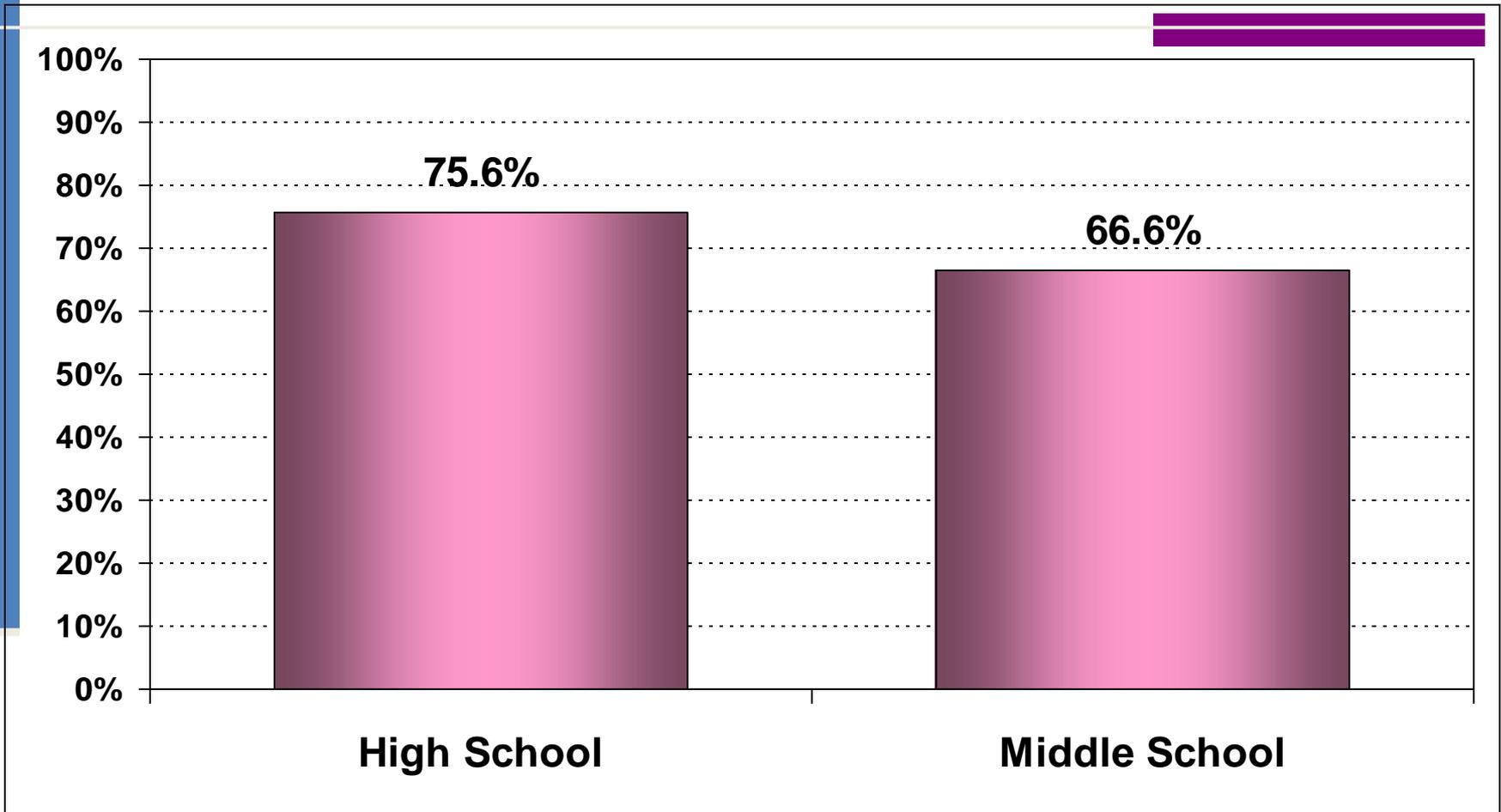
Maryland Public School Youth



Source: Maryland Department of Health and Mental Hygiene, Youth Tobacco Survey – Fall 2010.

Current Use of Flavored Cigar Products by Cigar Smokers - 2010

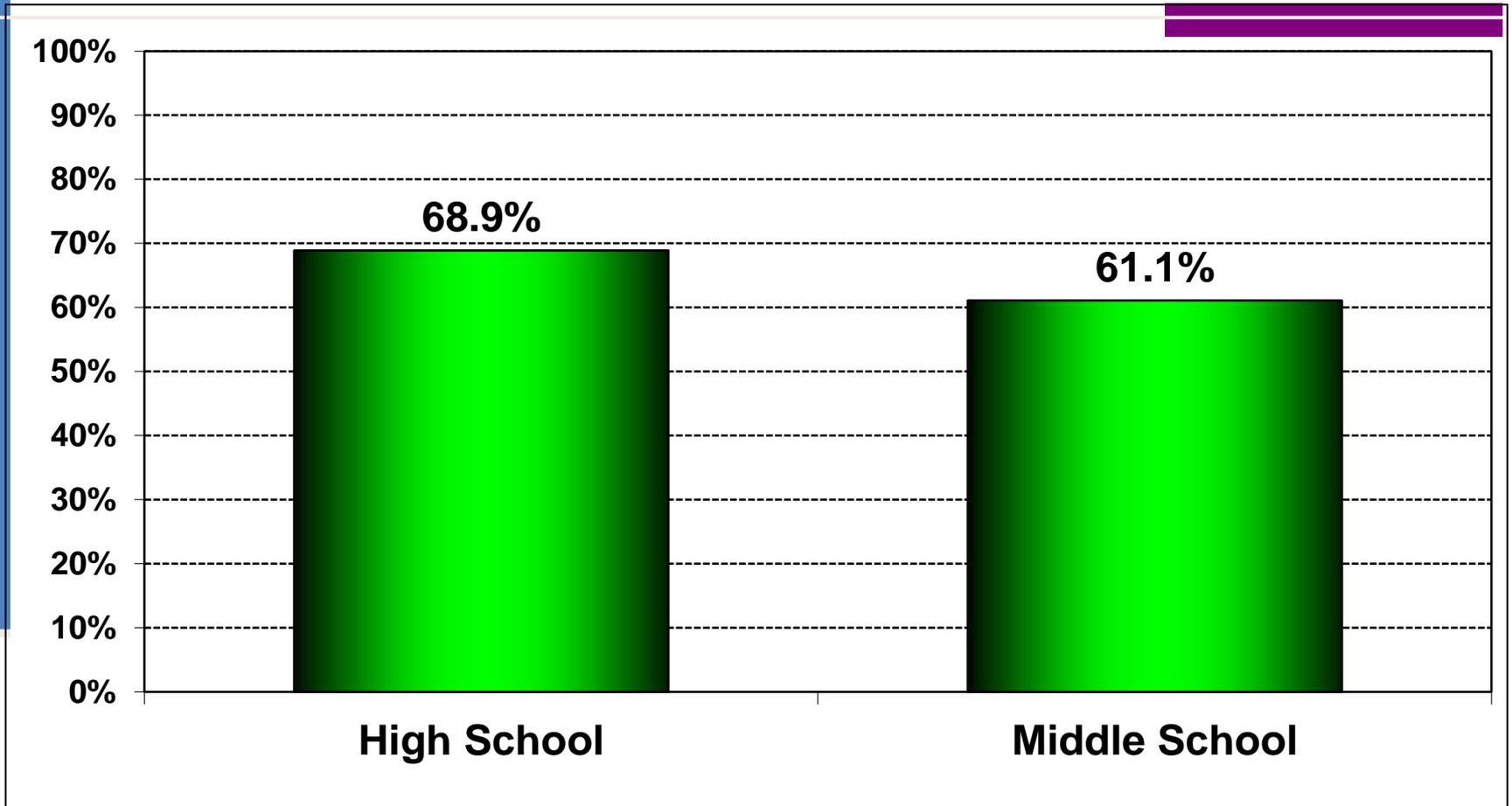
Maryland Public School Youth



Source: Maryland Department of Health and Mental Hygiene, Youth Tobacco Survey – Fall 2010. Current Flavored Cigars/Current Cigar Smokers

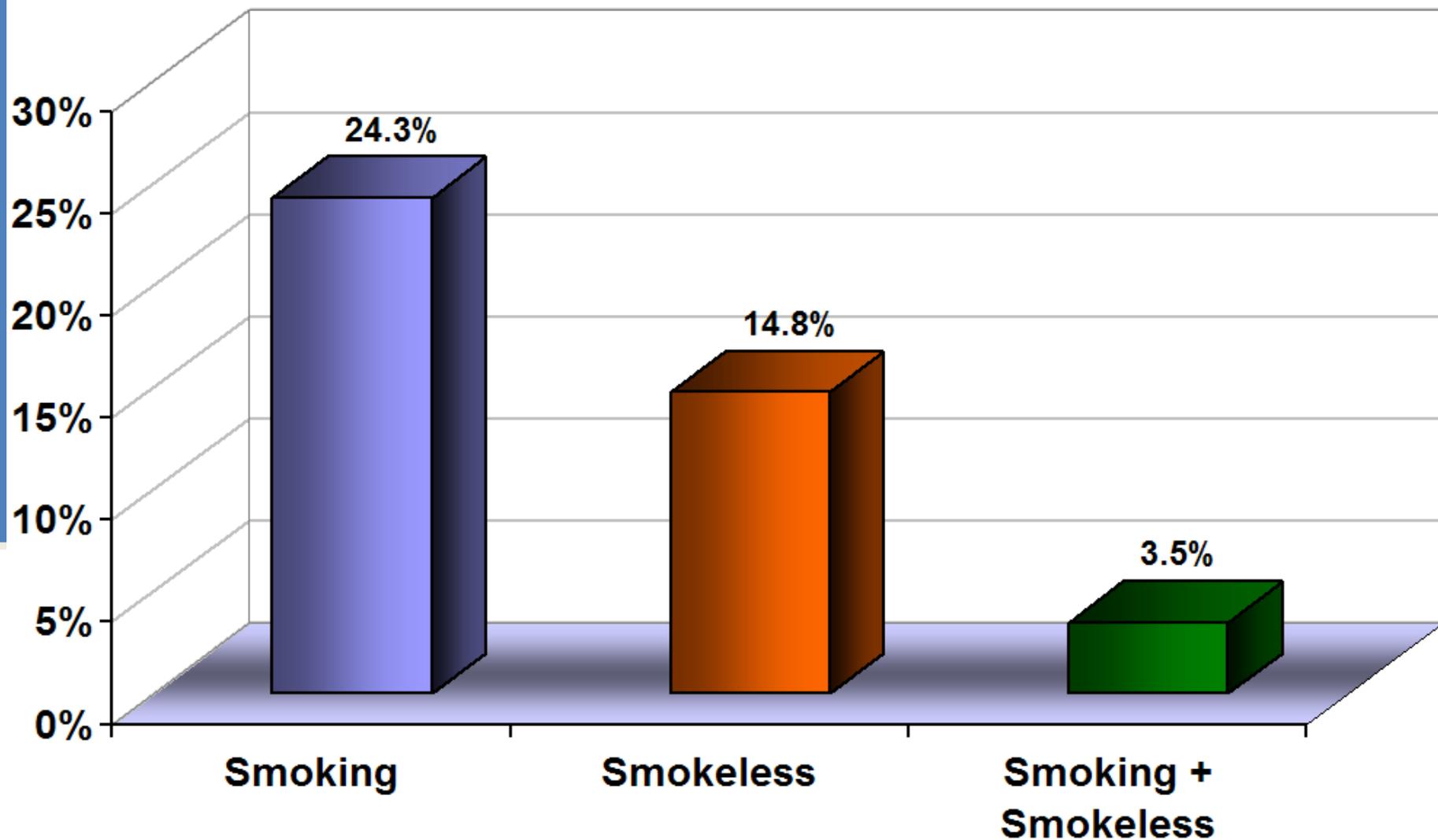
Current Use of Flavored Smokeless by Users of Smokeless Tobacco Products - 2010

Maryland Public High School Youth

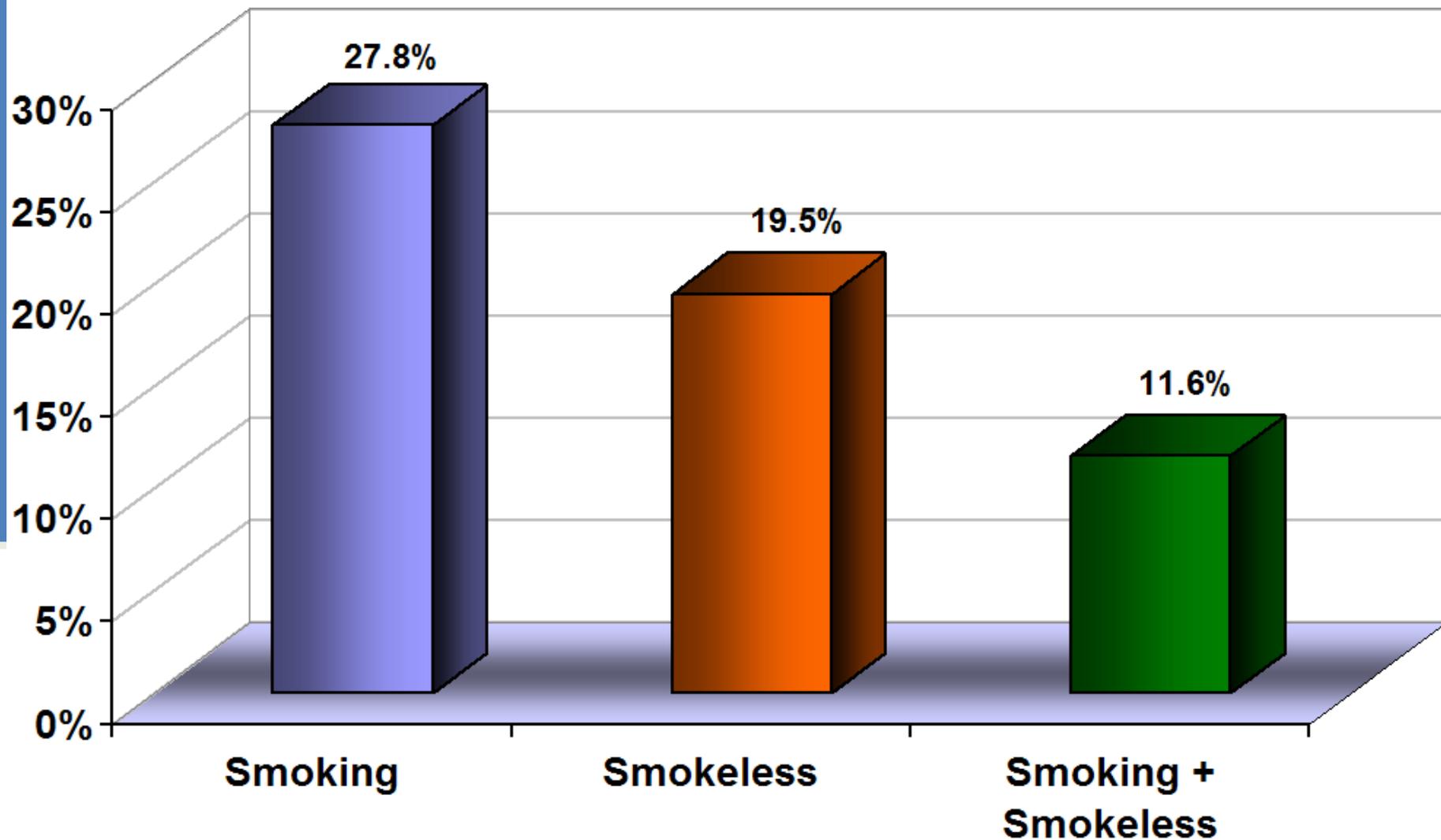


Source: Maryland Department of Health and Mental Hygiene, Youth Tobacco Survey – Fall 2010. Current smokeless tobacco use is any use of any smokeless tobacco product during the 30 days prior to the survey.

Current smoking, smokeless, and concomitant (smoking and smokeless) tobacco use rates among adult white males, 2006 Arkansas Adult Tobacco Survey



Current smoking, smokeless, and concomitant (smoking and smokeless) tobacco use rates among high school boys, 2005 Arkansas Youth Tobacco Survey

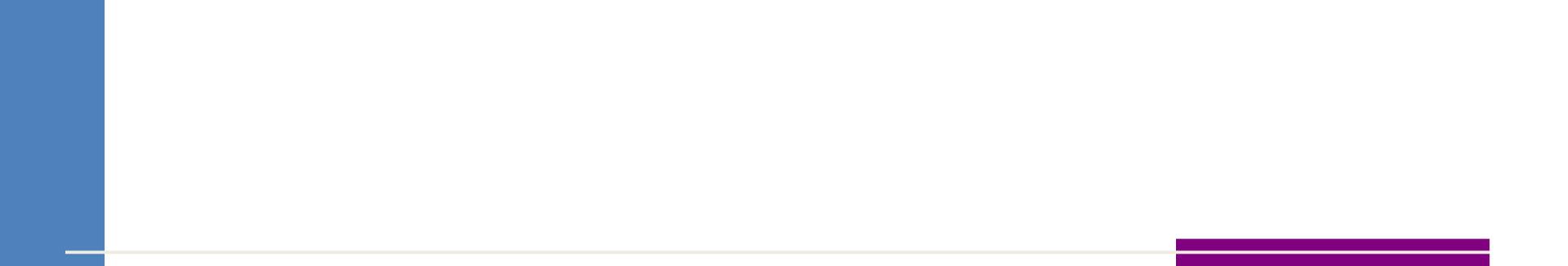


New Growth Products? -- Use MRTP/NGP interchangeable

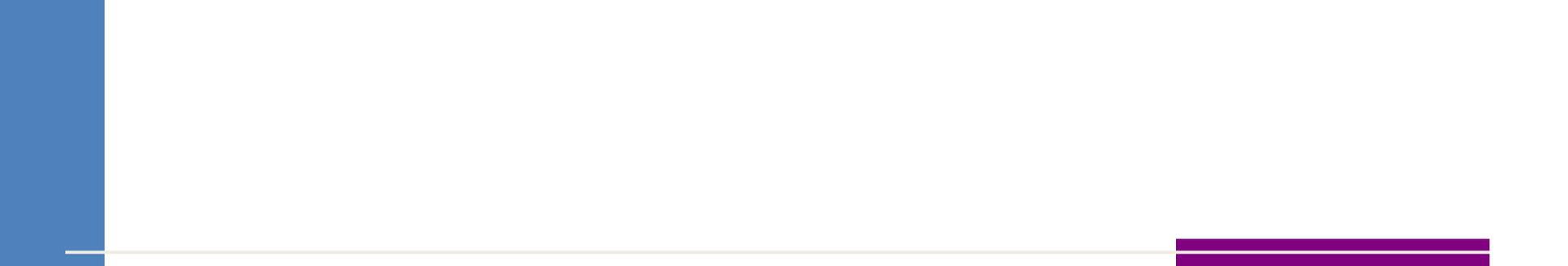
PMI's NGP Objectives



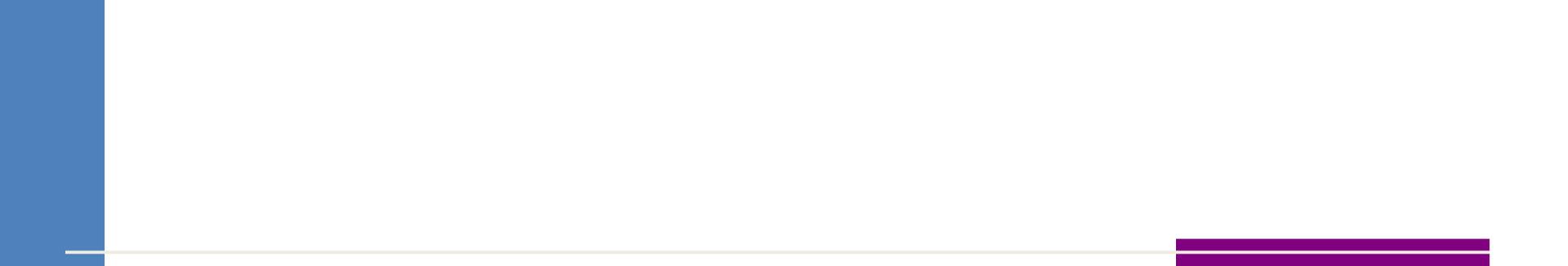
- Products acceptable to adult smokers of conventional cigarettes:
 - Taste and sensory experience
 - Ritual
- Robust scientific evidence of risk reduction:
 - Individual risk
 - Reduced risk to the population
 - Best practice systems
- Appropriate regulation for development, assessment, commercialization and consumer communication



“We (PMI) believe the elimination of combustion via tobacco heating and other innovative systems for aerosol generation is the most promising path to secure risk reduction.”



“We expect taste (for NGP) to be essentially at parity with conventional products for menthol variants and close to regular super-low tar cigarettes based on adult smoker panel evaluations.”



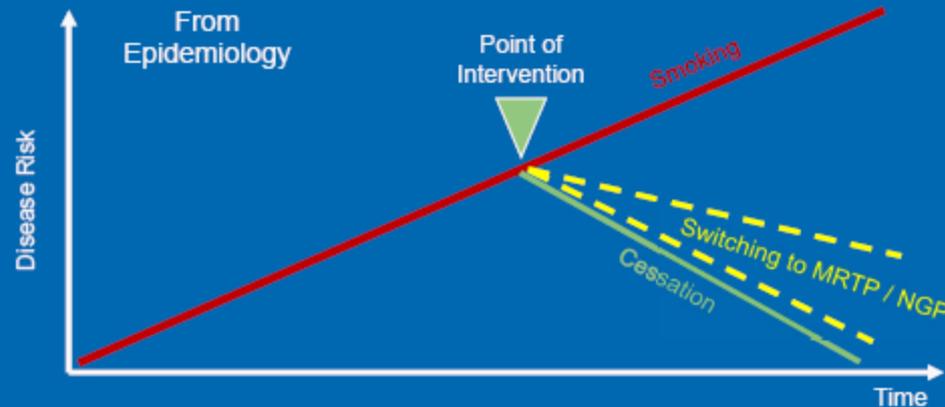
“Our approach to individual risk assessment is to use cessation as the benchmark.

The closer the clinical data derived from adult smokers who switched to an NGP resembles the data from those who quit, the more confident one can be that the product reduces the risk of disease. Our objective is to fall somewhere between the conceptual yellow lines ... shown and ideally approach the green line.”

Cessation as a Benchmark to Substantiate Risk Reduction

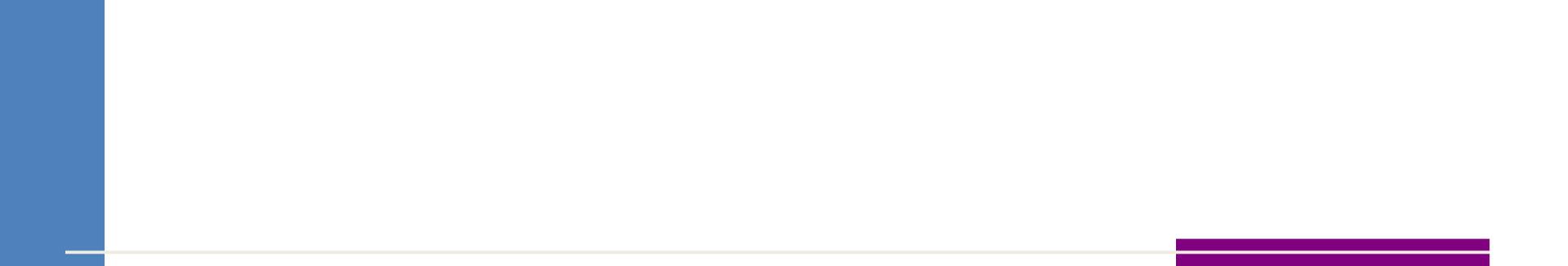


- The health risks of smoking and the reversal of risks after quitting smoking are well established



- “[T]he closer risks and exposures from the MRTP are to cessation products, the more confident a regulator can be in the chances for net public health benefit” – U.S. Institute of Medicine, 2011

Note: The descriptions in the chart are for illustrative purposes only



“We were very encouraged by the meeting (with the Center for Tobacco Products with the Food and Drug Administration) and although several details still need to be discussed, we remain comfortable with our current risk assessment approach.”

The FDA has Issued Draft Guidance

- Non-binding
- MRTPs may be valuable tools in promoting public health
- Generally in line with PMI's assessment approach
- Does not establish required levels of evidence
- Continued consultation necessary for more detailed guidance

“We are opting for one or two greenfield facilities in Europe.”

“...we envisage marketing our NGPs under our existing major trademarks such as *Marlboro.*”

“...we expect the first factory to be ready in 2015 or 2016 final data from clinical studies during the beginning of 2016 and a launch in the first markets between 2016 and 2017.”

Niconovum



FDA Authority

- Directive-Controls behavior of manufacturing, Menthol, Nicotine Levels
- Gatekeeper-Defines debate, agenda while keeping the gate closed to new products
- Conceptual-Ability to shape concepts and standards: MRTP Required Testing

Philip Morris USA

Flavor Ingredients - As of 6 - 21 - 11

Ingredient	Quantities not to Exceed the % weight in tobacco	Function
Cocoa & Cocoa Products	0.5	Flavor
Ethyl Vanillin	0.8	Flavor
Licorice Extract	0.8	Flavor
Orange Oil, Sweet	0.001	Flavor
Tangerine	0.005	Flavor
Vanilla Bean	0.001	Flavor
Vanillin	0.005	Flavor

FDA and Menthol



A WORLD OF FRESH TASTE

EXPLORE FRESH

W A R N I N G T O B E P L A C E D H E R E

This advertisement features four Marlboro cigarette packs standing on a reflective surface. From left to right, the packs are: Silver Mint (white with a green chevron), Ice Frost (white with a blue chevron), Silk Fresh (dark blue with a blue chevron), and Juice Fresh (black with a blue chevron). The background is a soft, hazy blue. The text 'A WORLD OF FRESH TASTE' is positioned at the bottom left, and 'EXPLORE FRESH' with a small globe icon is at the bottom right. A warning line is at the very bottom.

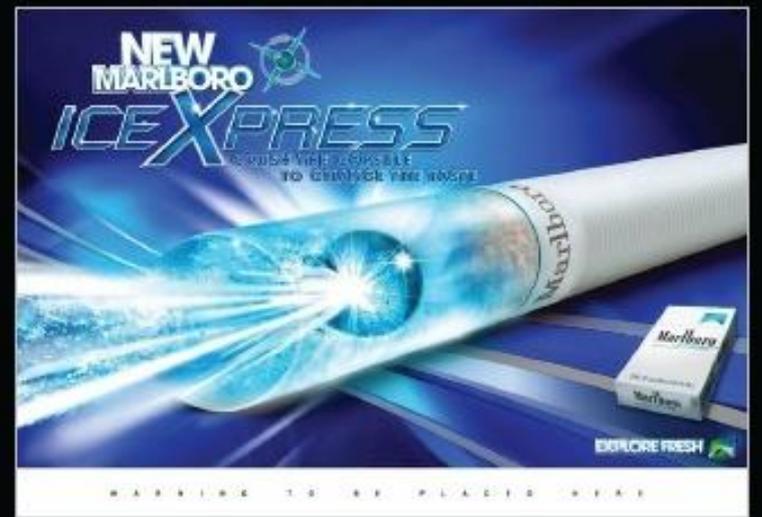


NEW
SILVER MINT
UNIQUE COOL MENTHOL STRIPE

EXPLORE FRESH

W A R N I N G T O B E P L A C E D H E R E

This advertisement shows a close-up of a Marlboro Silver Mint cigarette. The cigarette is white with a green chevron on the filter. The background is a vibrant green with light rays emanating from behind the cigarette. The text 'NEW SILVER MINT' and 'UNIQUE COOL MENTHOL STRIPE' is at the top. 'EXPLORE FRESH' is at the bottom right, and a warning line is at the very bottom.



NEW
MARLBORO ICE Xpress
COOL MINT FLAVOR
TO COOL YOUR MOUTH

EXPLORE FRESH

W A R N I N G T O B E P L A C E D H E R E

This advertisement features a Marlboro Ice Xpress cigarette. The cigarette is white with a blue chevron on the filter. The background is a vibrant blue with light rays emanating from behind the cigarette. The text 'NEW MARLBORO ICE Xpress' and 'COOL MINT FLAVOR TO COOL YOUR MOUTH' is at the top. 'EXPLORE FRESH' is at the bottom right, and a warning line is at the very bottom.

Menthol

The horse was out of the gate (not FDA Gate Keeping)

- A Washington based process led to a Washington based result (gridlock)
- The tobacco control community not central as a stakeholder as the AIDS community was in 1980s. State and local tobacco control isolated from the process
- Lack of support of the African American Community
- Political amateurism to the politics of menthol by the administration

Recent Package Changes?

PALL MALL – RJ Reynolds

Old

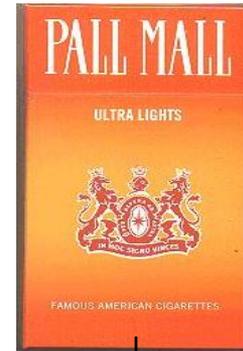
Full Flavor



Lights



Ultra Lights



New

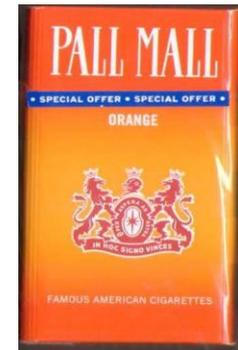
Red



Blue



Orange



Tar: 16mg

Tar: 12mg

Tar: 5mg

Parliament



Old Pack
 Parliament Full Flavor
 Parliament Lights
 Parliament Lights 100's
 Parliament Menthol Full Flavor
 Parliament Menthol Lights
 Parliament Menthol Lights 100's
 Parliament Menthol Ultra Lights
 Parliament Ultra Lights

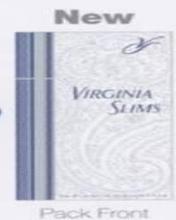
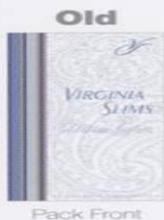
New Pack Identifier

Parliament (Blue Pack)
 Parliament (White Pack)
 Parliament (White Pack) 100's
 Parliament Menthol (Green Pack)
 Parliament Menthol (White Pack)
 Parliament Menthol (White Pack) 100's
 Parliament Menthol Silver Pack

New Pack Available In

Box
 Box and Soft Pack
 Box and Soft Pack
 Box
 Box
 Box
 Box
 Box

Virginia Slims



Old Pack
 Virginia Slims Lights
 Virginia Slims Ultra Lights
 Virginia Slims Menthol
 Virginia Slims Menthol Lights
 Virginia Slims Menthol Ultra Lights
 Virginia Slims 120's Luxury Lights
 Virginia Slims 120's Menthol Ultra Lights
 Virginia Slims 120's Menthol Luxury Lights
 Virginia Slims 120's Menthol Silver Pack
 Virginia Slims Superslims Lights
 Virginia Slims Superslims Menthol Lights

New Pack Identifier

Virginia Slims Gold Pack
 Virginia Slims Silver Pack
 Virginia Slims Menthol
 Virginia Slims Menthol Gold Pack
 Virginia Slims Menthol Silver Pack
 Virginia Slims 120's Gold Pack
 Virginia Slims 120's Silver Pack
 Virginia Slims 120's Menthol Gold Pack
 Virginia Slims 120's Menthol Silver Pack
 Virginia Slims Superslims Gold Pack
 Virginia Slims Superslims Menthol Gold Pack

New Pack Available In

Box
 Box
 Box and Soft Pack
 Box
 Box
 Box
 Box
 Box
 Box
 Box
 Box

L&M



Old Pack
 L&M Full Flavor
 L&M Full Flavor 100's
 L&M Lights
 L&M Lights 100's

New Pack Identifier

L&M
 L&M 100's
 L&M Blue Pack
 L&M Blue Pack 100's

New Pack Available In

Box
 Box
 Box
 Box

Basic



Old Pack
 Basic Full Flavor
 Basic Full Flavor 100's
 Basic Lights
 Basic Lights 100's
 Basic Menthol Lights
 Basic Menthol Lights 100's
 Basic Menthol Ultra Lights
 Basic Menthol Ultra Lights 100's
 Basic Ultra Lights
 Basic Ultra Lights 100's

New Pack Identifier

Basic
 Basic 100's
 Basic Gold Pack
 Basic Gold Pack 100's
 Basic Menthol Gold Pack
 Basic Menthol Gold Pack 100's
 Basic Menthol Silver Pack
 Basic Menthol Silver Pack 100's
 Basic Blue Pack
 Basic Blue Pack 100's

New Pack Available In

Box and Soft Pack
 Box
 Box
 Box and Soft Pack
 Box and Soft Pack

The following packings will remain unchanged:

Virginia Slims*
 Virginia Slims Superslims
 *Available in Box and Soft Pack

Virginia Slims Superslims Menthol
 L&M Bold

L&M Bold 100's
 L&M Menthol

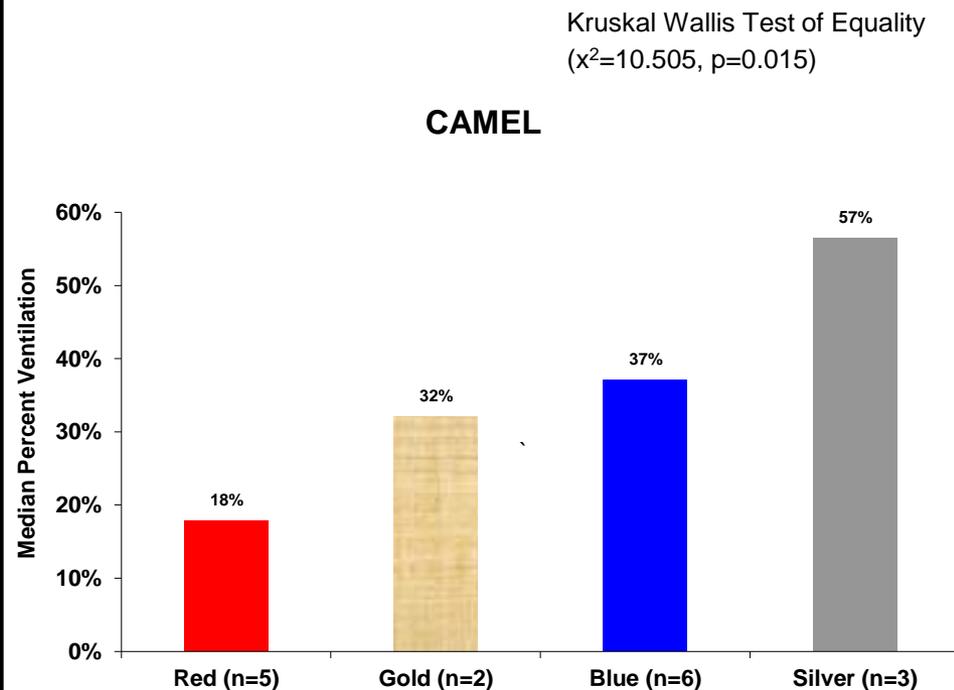
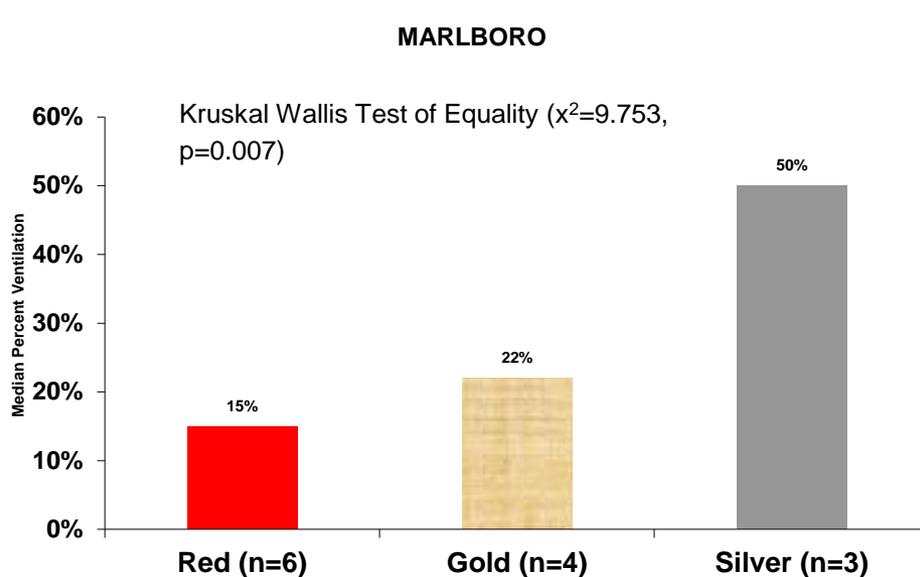
L&M Menthol 100's
 Basic Menthol*

Basic Menthol 100's*
 Basic Non-Filter Soft Pack

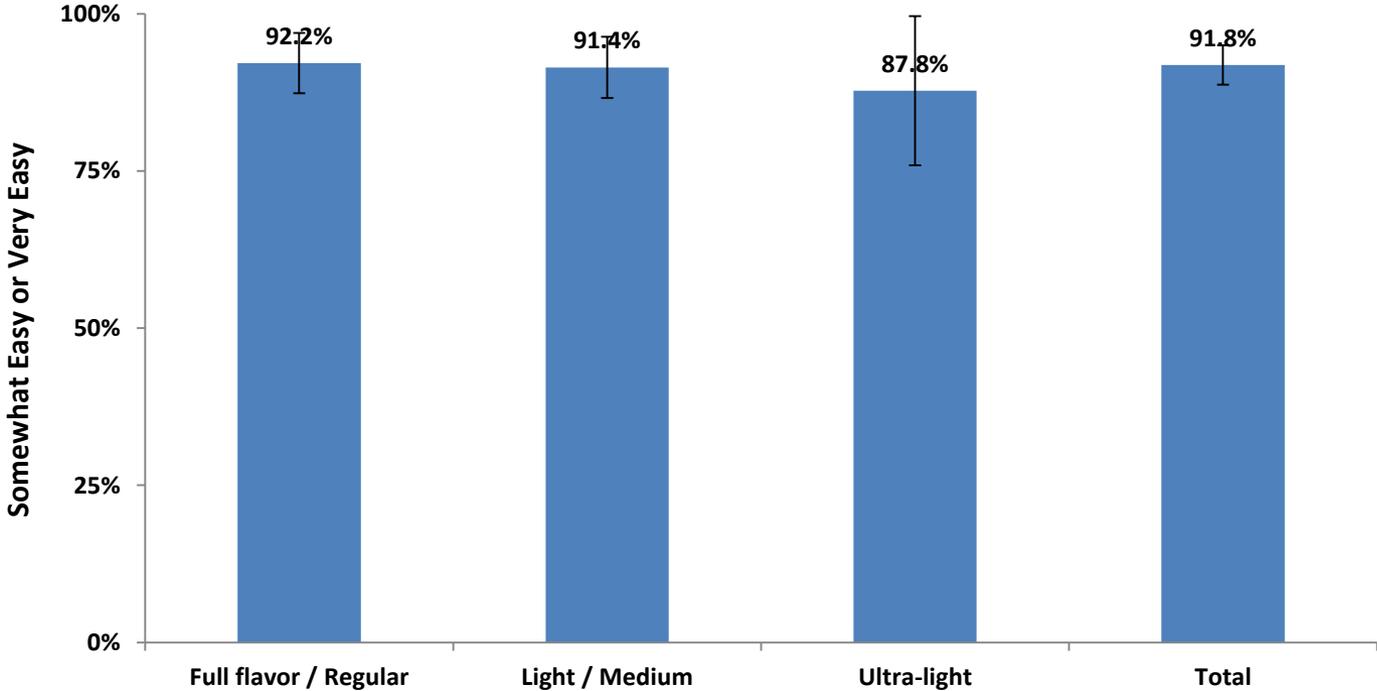
FOR TRADE USE ONLY. NOT TO BE SHOWN OR DISTRIBUTED TO CONSUMERS.

Percent Ventilation by Cigarette Package Color

(ventilation is the principal predictor of 't/n' machine yield)

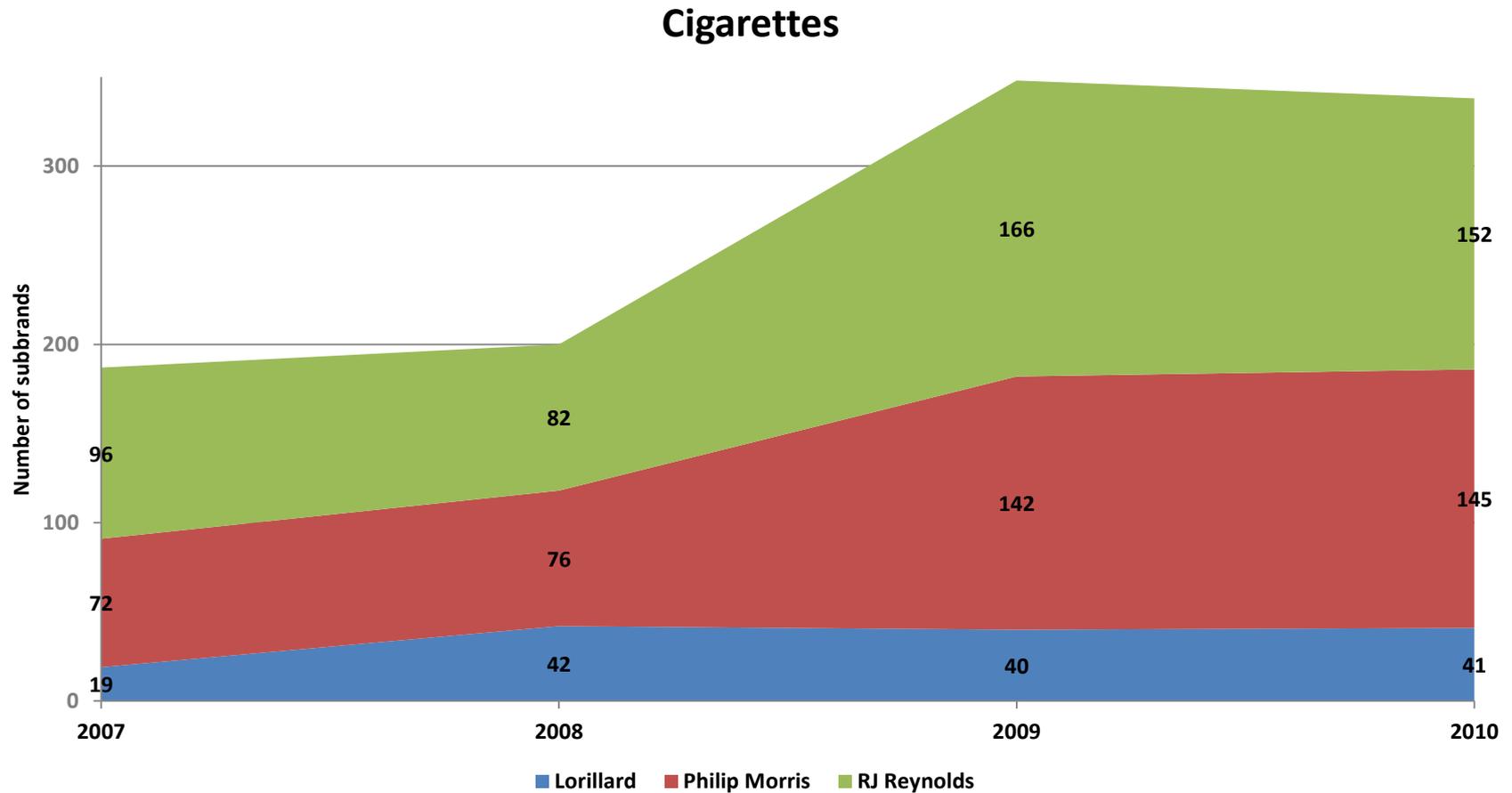


Brand Recognition by Banned Descriptors



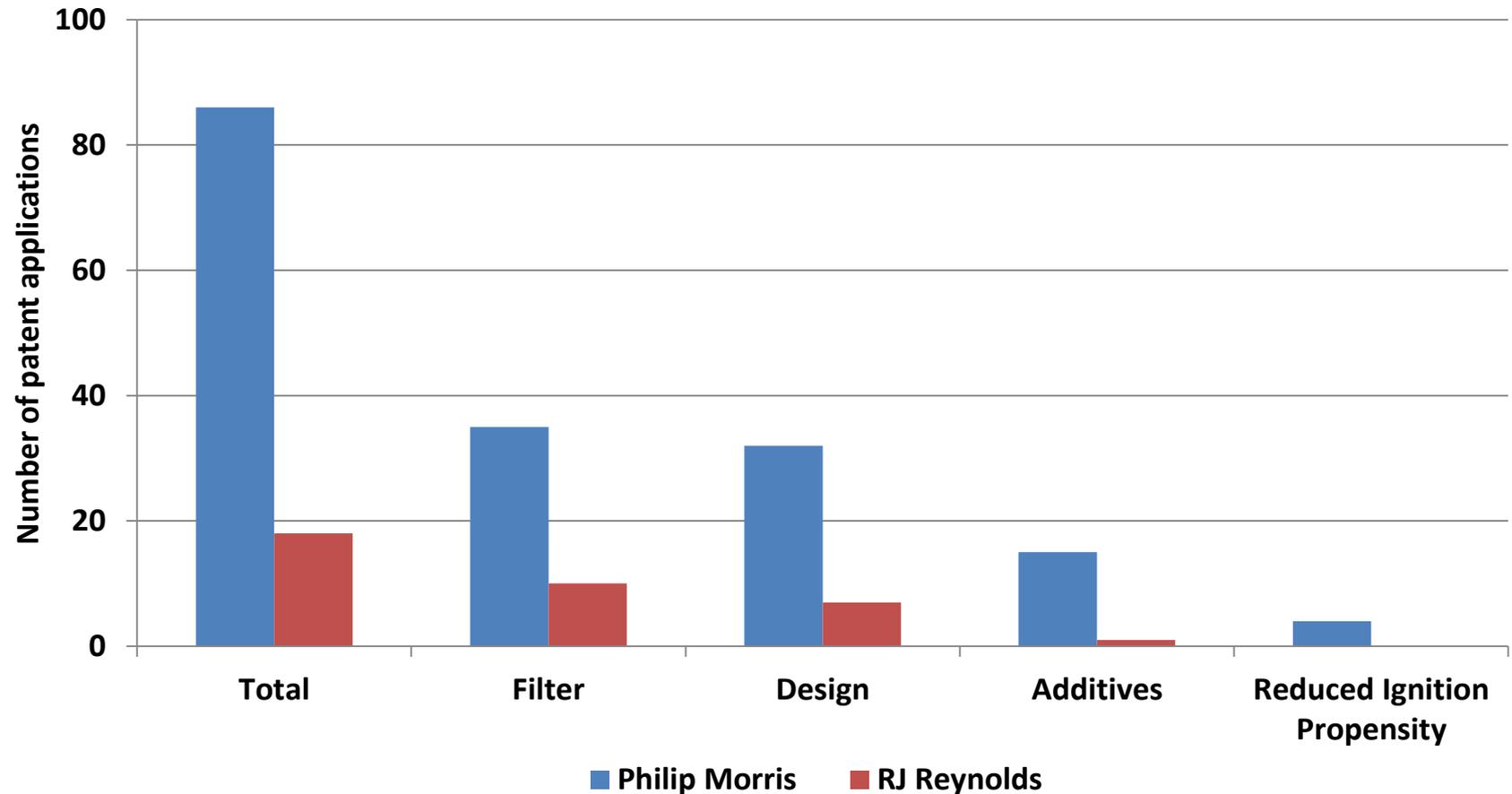
In the past six months, how easy has it been for you to identify your usual brand of cigarettes?

Numbers of Cigarette Sub-brands on the Massachusetts Market, 2007 - 2010



Data source: Massachusetts Tobacco Disclosures Database

U.S. Patent Applications by Cigarette Manufacturers Since February 15, 2007



Substantially Equivalent to What? -Section 905(j)



Predicate Product



or



Predicate Product

Tobacco Industry Applications for Products to FDA April 2012

Product	Applies	Approval/Denial
Existing/SE	3,622	0
New Products	0	0
MRTPs	8	0

The New York Times

Rules Delayed, Governing Denied

Only Mr. Obama's leadership can ensure that important new regulations take effect

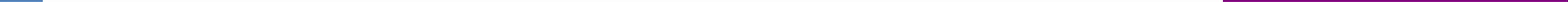
It has been 19 months since President Obama signed into law the Food Safety Modernization Act, the first overhaul of the Food and Drug Administration's food safety laws since the 1930s. But if you think the food supply has become markedly safer since then, think again.

The F.D.A. rules needed to carry out the law are still held up as a review by the White House's Office of Management and Budget enters its eighth month. While coordinating suggestions from various agencies can take time, a delay of eight months and counting lends credence to the suspicions of consumer advocates who think election-year politics are at play, with Democrats trying to avoid Republican charges that rules kill jobs.

The budget office denies this, and can point to many rules that have been approved, including a crucial one reducing mercury emissions from power plants. But several important rules, like those on food safety, remain in limbo. Such delays call into question the Obama administration's commitment to reforms that are needed to make government work better and more effectively. Here are some regulations that must not be allowed to languish:

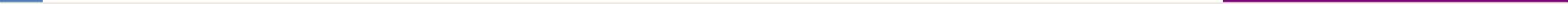
The Family Smoking Prevention and Tobacco Control Act

- The states gave FDA authority and relinquished the states power under the Constitution
- FDA is a highly centralized, non-transparent rule making body that must treat the tobacco control community not as a partner but as any interested party
- FDA must maintain strict neutrality like a court but unlike a court is subject to undue political pressures



U.S. Federal Court Decision on
Violation of the **Racketeer Influenced and Corrupt Organizations Act (RICO)**

“The tobacco manufacturers have conducted longstanding and continuing fraudulent efforts to deceive the American public.” Judge Kessler (2006)



FDA TPSAC Statement in Menthol Report

TPSAC received useful comments from the non-voting members, tobacco manufacturers; TPSAC acknowledged their collegial input

NB: TPSAC was sued two months prior by one member non voting company member

History of Tobacco Control in America

A Community Based Social Movement based on science but driven by social democratic principles of human rights and social justice

- Protection of children from addiction
- Protection of Non Smokers from the harm of second hand smoke
- Treatment of smokers dependence on tobacco and disease
- Confronting the Injustices of the industry that knowingly lied and willing sold a harmful product to our citizens particularly those who are disadvantaged

American Public Health Improvement Begins in our Communities

- Local Research: Community based, salient, policy focused, strong health communications value
- Local Policy Outcomes : New Local Laws that move FDA and Washington
- State and local lawsuits that bring justice denied by political pressure
- Local Shifts in Public Opinion, Changes in Social Norms and Individual Behavior

- 
- It is time to reverse to halt and reverse the growing accumulation of power and authority to the central government in Washington and to return the power of decision making to the people in their own local communities”

The Tea Party? Or?

Creating Child Proof Tobacco Markets in Communities by 2020

Goal

No child is able to initiate use of a tobacco product through the adoption of science based and socially acceptable federal, state and local policies that:



MASSACHUSETTS
OPERATION STOREFRONT -1998-

Comprehensive Child Proof Market Policies

- Limit number of licenses. 2 expire, 1 issued
- No outlets near schools or playgrounds
- Ban on sale of flavored OTPs
- Require Child Proof Packaging (2020)
- Ban TPs that cause addiction among children (2030)

Why are only Camel dissolvables not cigarettes sold in childproof packs?





- 
-
- “All of us wished we lived in a more tranquil time but we don’t. And if our times are difficult and perplexing , so they are filled with challenges

Robert F. Kennedy



- 
- 
- 
- The problem is not the FDA's or Washington's
– It's ours!!!
 - The solution is not found in the “Beltway” but in America's communities
 - As Americans, we must set moral limits on the tobacco marketplace and require accountability from federal agencies to exercise the power the states gave them and we must act!

April 15, 1994



EX #???

"They can crush a few flowers, but they cannot hold back the springtime."

Sister Pat Farrell, Leadership Conference of Women Religious 8/12



PEACE
LOVE + JOY

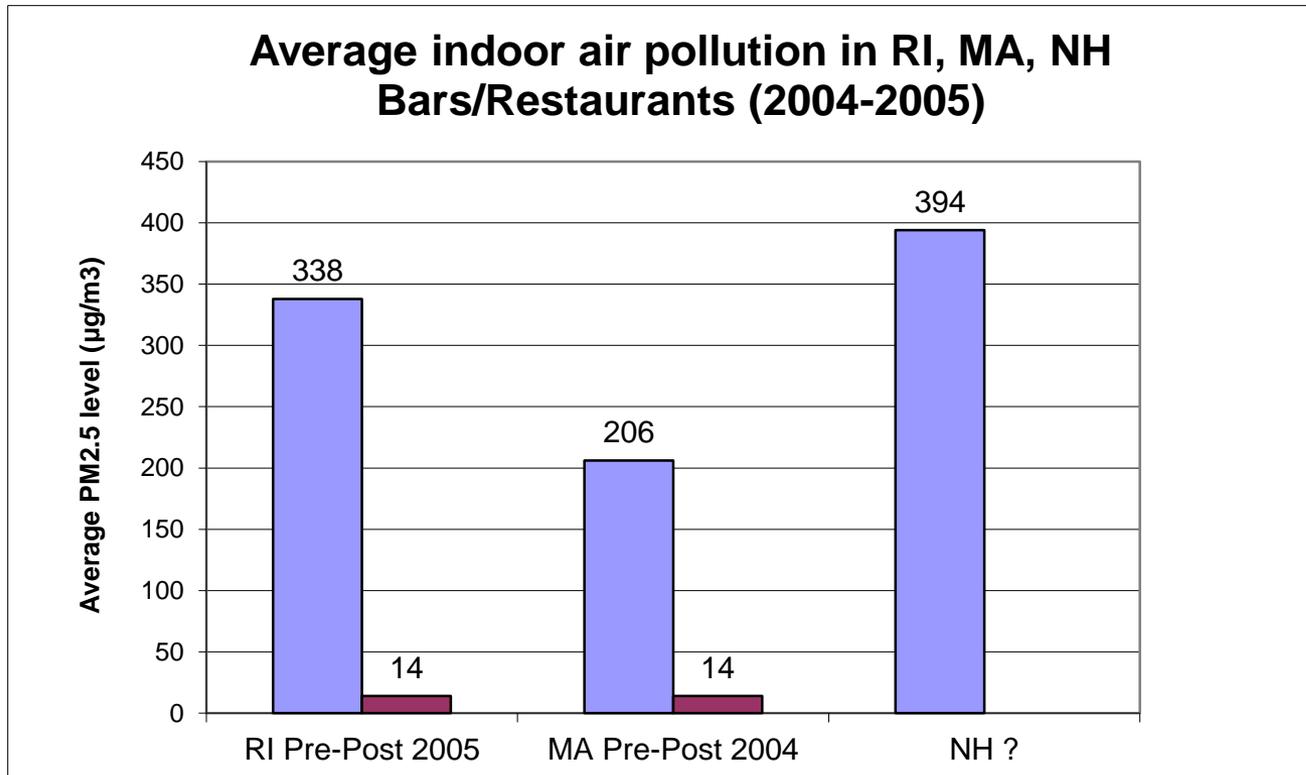


♥ Greg & Susan

NRT and other Factors Associated with Likelihood of Smoking Relapse

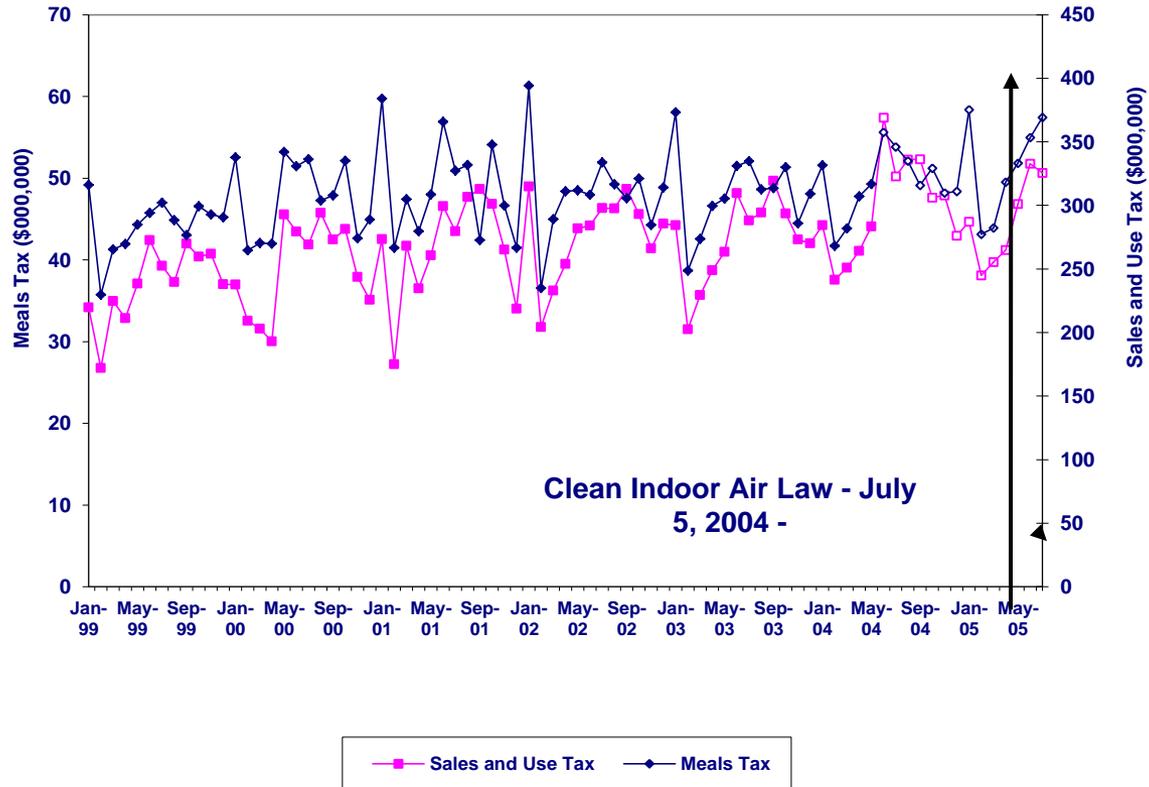
	NRT defined as any reported use Odds Ratio (95% CI)		
Time since quit smoking:	≤ 2 Years	≤ 1 Year	≤ 6 months
Predictor variable: Referent			
Prior heavy dependent smokers			
Use of NRT only : No use of NRT or professional help	2.68 (1.40 – 5.11)	2.62 (1.22 – 5.62)	3.53 (1.50 – 8.32)
Use of NRT and professional help : No NRT or professional help	0.94 (0.40 – 2.22)	0.98 (0.37 – 2.56)	2.03 (0.62 – 6.58)
Prior light dependent smokers			
Use of NRT Only : No use of NRT or professional help	1.38 (0.34 – 5.67)	1.57 (0.29 – 8.53)	0.39 (0.06 - 2.43)
Use of NRT and professional help : No use of NRT or professional help	2.08 (0.73 - 5.85)	1.87 (0.57 – 6.14)	3.95 (0.94 – 16.5)
Prior smoking abstinence*			
Over 44 years of age : 18 to 44 years of age	0.46 (0.29 - 0.73)	0.49 (0.28 – 0.86)	0.44 (0.21 – 0.90)
	0.68 (0.40 – 1.16)	0.57 (0.33 – 0.97)	0.41 (0.22 – 0.80)

Secondhand Smoke (SHS) Massachusetts Pre/Post



Massachusetts Clean Indoor Air Law Pre / Post Taxation

Massachusetts Monthly Meals Tax Collections



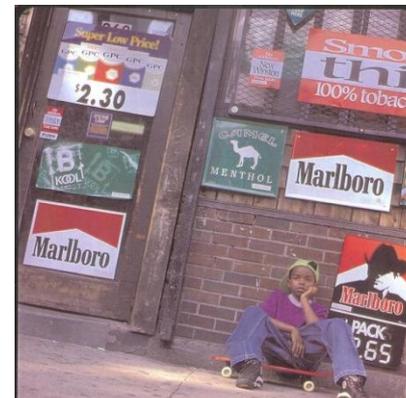
Methods

Equipment:

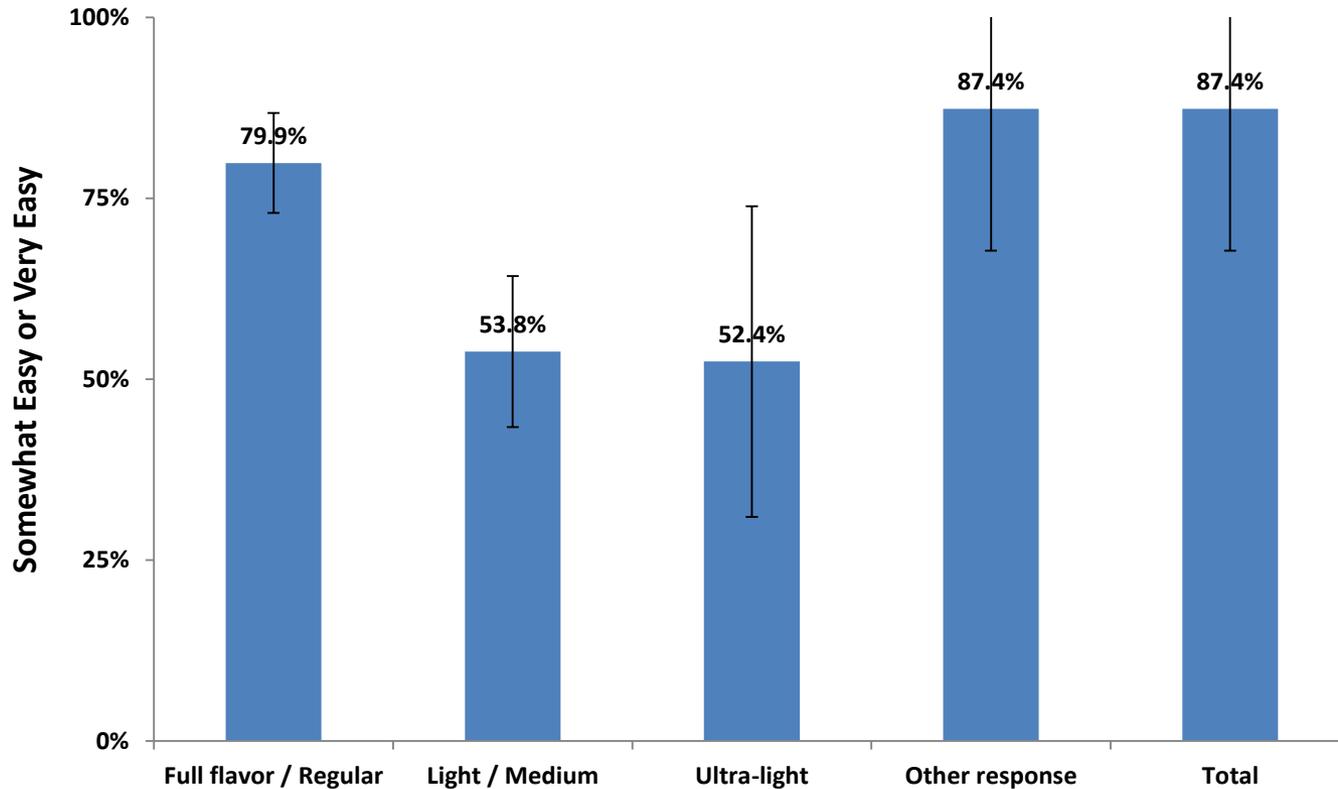
- A camera with incorporated GPS (<http://www.geospatialexperts.com/productadv.html>)

Study Design:

- Cross-sectional assessment of clustering of Tobacco billboards (or large posters on buildings or other structures) and store-front posters and their relationship to schools using GPS to generate spatial coordinates.



Brand Identification by Package Color



What is the main color on the cigarette package of the brand that you smoked most often during the past 30 days? (Percent correct identification)

GPS -Protocol

Billboards:

- ❑ Photos and GPS coordinates of billboards 1000 feet, (~300m) around schools
- ❑ Photos and GPS coordinates of youth locations within the same buffer zone (e.g. parks, playgrounds, sport arenas)

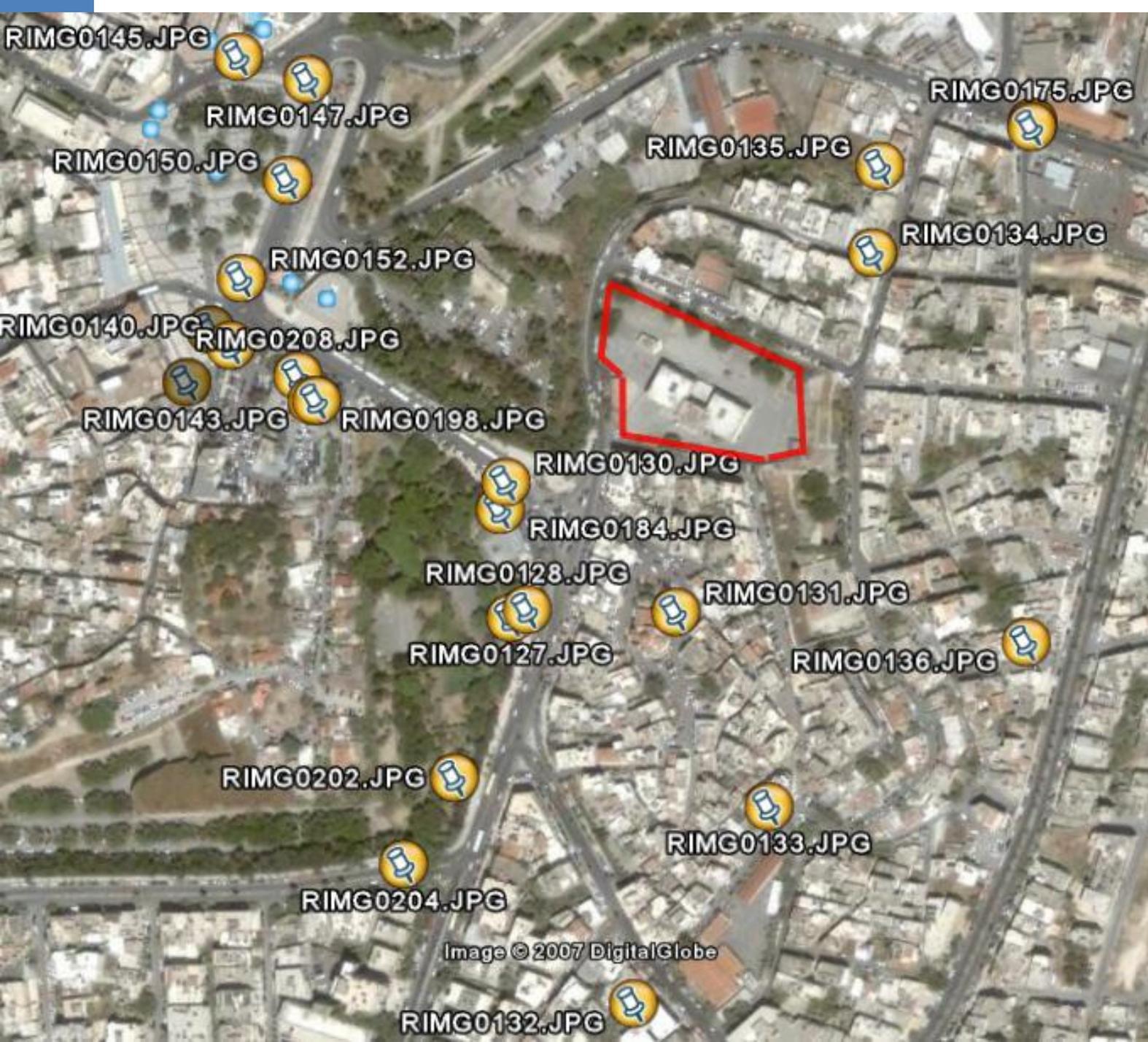
Point of Purchase:

- ❑ Photos and GPS coordinates of the exterior
- ❑ Questionnaire

Equipment

- ❑ Integrated Digital camera+GPS system
- ❑ Google Earth





1st Lyceum

1st
Gymnasium

18 POP

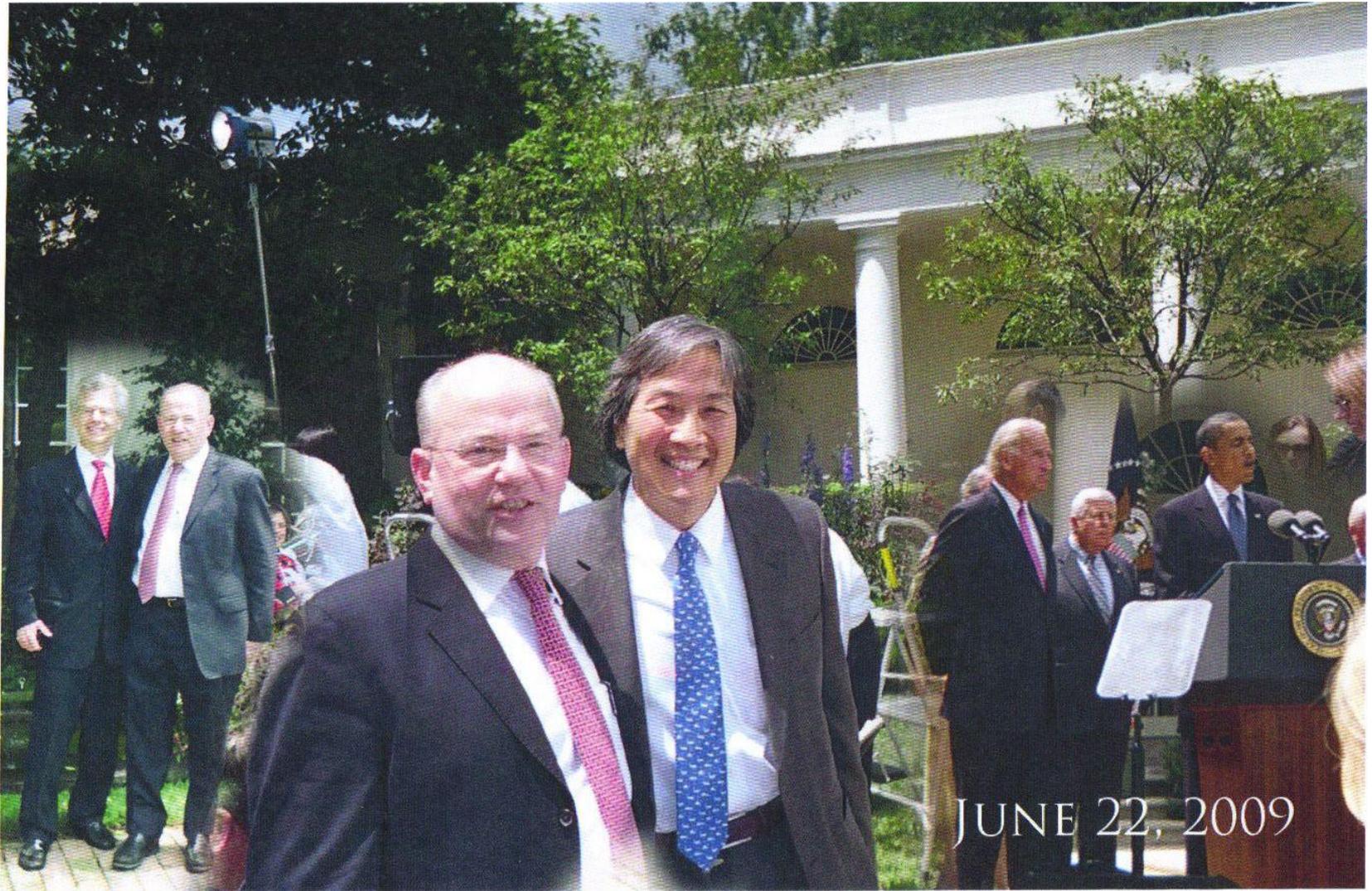
2 Bus stops

2 billboards

Measuring Air Quality

- Cigarettes, cigars and pipes are major emitters of respirable suspended particles less than 2.5 microns ($PM_{2.5}$) in diameter that are easily inhaled deep into the lungs
- **TSI SidePak AM510 Personal Aerosol Monitor (weight: 1 lb)**
- This device is a real-time laser photometer with a built-in sampling pump that measures airborne particle mass-concentration





JUNE 22, 2009



Mean Percent Ventilation by Lights and Color Descriptors

PM Document ³	Light		Ultralight
Cigarette Design	20-30%		45-70%
Year:2009	Light		Ultralight
Marlboro	29%		46%
Camel	32%		56%
Newport	23%		-
Years: 2010-2011	Blue	Gold	Silver
Marlboro		28-29%	47-50%
Camel	29-34%	38-40%	40-42%
Newport	28%	34%	-

Data source: Annual Reports to Massachusetts Department of Public Health^{2,5}



Apple, 1984



Apple, 2012