

FDA Oversight of Tobacco Products: Menthol and Native Hawaiians, Pacific Islanders and Asian Americans

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**APPEAL 15th Anniversary: Talk Story: Sharing
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June 3rd, 2009

San Francisco, California

FDA Oversight of Tobacco

- June 22nd, 2009 OBAMA signed in law the Family Smoking Prevention and Tobacco Control Act.
- 12- Person Tobacco Products Scientific Advisory Committee (3 non-voting tobacco industry representatives)
 - 1 year a report on menthol
 - Dissolvables
 - New products; harm reduction and e-cigarettes

Tobacco Prevention Opportunities

- **Ban all remaining tobacco-brand sponsorships of sports and entertainment events**
- **Ban free giveaways of any non-tobacco items** with the purchase of a tobacco product or in exchange for coupons or proof of purchase,
- **Limit advertising in publications with significant teen readership** as well as outdoor and point-of-sale advertising, except in adult-only facilities, to black-and-white text only,

Tobacco Prevention Opportunities

- **Ban outdoor advertising near schools and playgrounds** after further FDA review,
- **Restrict vending machines** and self-service displays to adult-only facilities, and
- **Require retailers to verify age for all over-the-counter sales** and provide for federal enforcement and penalties against retailers who sell to minors.

Tobacco Prevention Opportunities

- **Requires detailed disclosure of ingredients, nicotine and harmful smoke constituents**
- **Allows FDA to require changes to tobacco products to protect the public health**
- **Prohibits the use of descriptors, such as “light”, “mild” and “low,” to characterize a product on labels or in advertising.**

Tobacco Prevention Opportunities

- **Requires bigger, graphic health warnings** –The law requires graphic warning labels that cover the top 50% of the front and rear panels of the cigarette pack
- **Fully funds FDA regulation of tobacco products through a user fee on manufacturers of cigarettes, cigarette tobacco and smokeless tobacco**

Tobacco Prevention Opportunities

- **Preserves state and local authority** – The law does not preempt state and local governments from enacting other tobacco control measures, including tobacco taxes, smoke-free workplace laws and fire-safety standards for cigarettes.

Menthol and the FDA: A Missed Opportunity

- cigarette or any of its component parts (including the tobacco , filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. (HR 1256, Sec. 907, (a) (1))

The Push Back

- “Cigarette Bill Treats Menthol with Leniency”. Stephanie Saul’s NY Times Article (May 13, 2008)
- Robert G. Robinson captured the matter succinctly: “I think we can say definitively that menthol induces smoking in the African-American community and subsequently serves as a direct link to African-American death and disease”

The Push Back

- National African American Tobacco Network and its Executive Director Bill Robinson spearheaded the work with Louis Sullivan that gave rise to the unprecedented move by seven former U.S. Secretaries of Health, Education, and Welfare to write a stinging letter to House and the Senate.

The Push Back

- “To make the pending tobacco legislation truly effective, menthol cigarettes should be treated the same as other flavored cigarettes. Menthol should be banned so that it no longer serves as a product the tobacco companies can use to lure African American children.
- “We do everything we can to protect our children in America, especially our white children. It’s time to do the same for all children.”
(Califano, et al., 2008)

The Push Back

- **Congressional Black Caucus (CBC)**. By late June, Donna Christensen (D. V.I.) had picked up the ball and help to craft the menthol amendment
- **Harvard researchers**, publishing in the *American Journal of Public Health*, documented that the **tobacco industry has been manipulating the dose of menthol in cigarettes** to ensure the uptake and continued use, especially by the young people and other vulnerable populations for many years.

The Push Back

- The national news coverage
- The letter from the seven former Secretaries' of Health
- The advocacy work of the NAATPN
- The involvement of the Congressional Black Caucus
- The release of the Harvard study
- Taken together forced a major amendment to the FDA oversight Bill.

The Result: Amended FDA Bill

- `(e) Menthol Cigarettes-
- `(1) REFERRAL; CONSIDERATIONS- Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under section 917(a), the Secretary shall refer to the Committee for report and recommendation, under section 917(c)(4), the issue of the impact of the use of menthol in cigarettes on the public health, including such use among African Americans, Hispanics, and other racial and ethnic minorities. (HR 1256, Sec. 907 (e) (1))

The Ultimate Candy Flavoring; Menthol Helps The Poison Go Down Easier

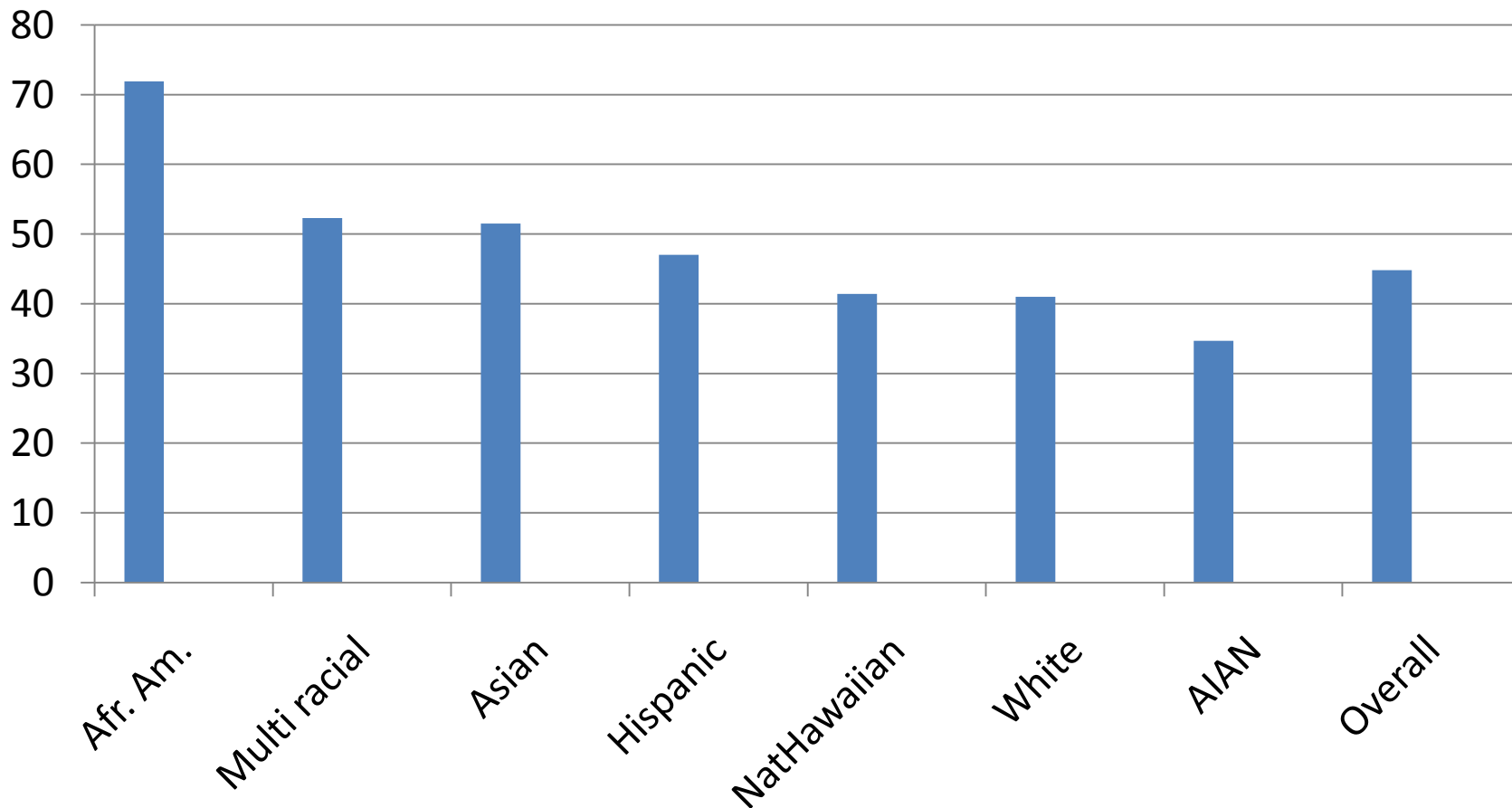
- Chief Constituent of Peppermint Oil; Minty Taste, Fresh Odor,
- Cooling Sensation; activates taste buds; increases throat grab
- Anesthetic effects; Mimics Bronchial Dilatation
- Independent Sensory Activation Neurotransmitters
- Increases Salivary Flow; Transbuccal Drug absorption
- Greater Cell Permeability (Ferris, 2004; Benowitz, 2004;

Who uses Menthol Cigarettes?

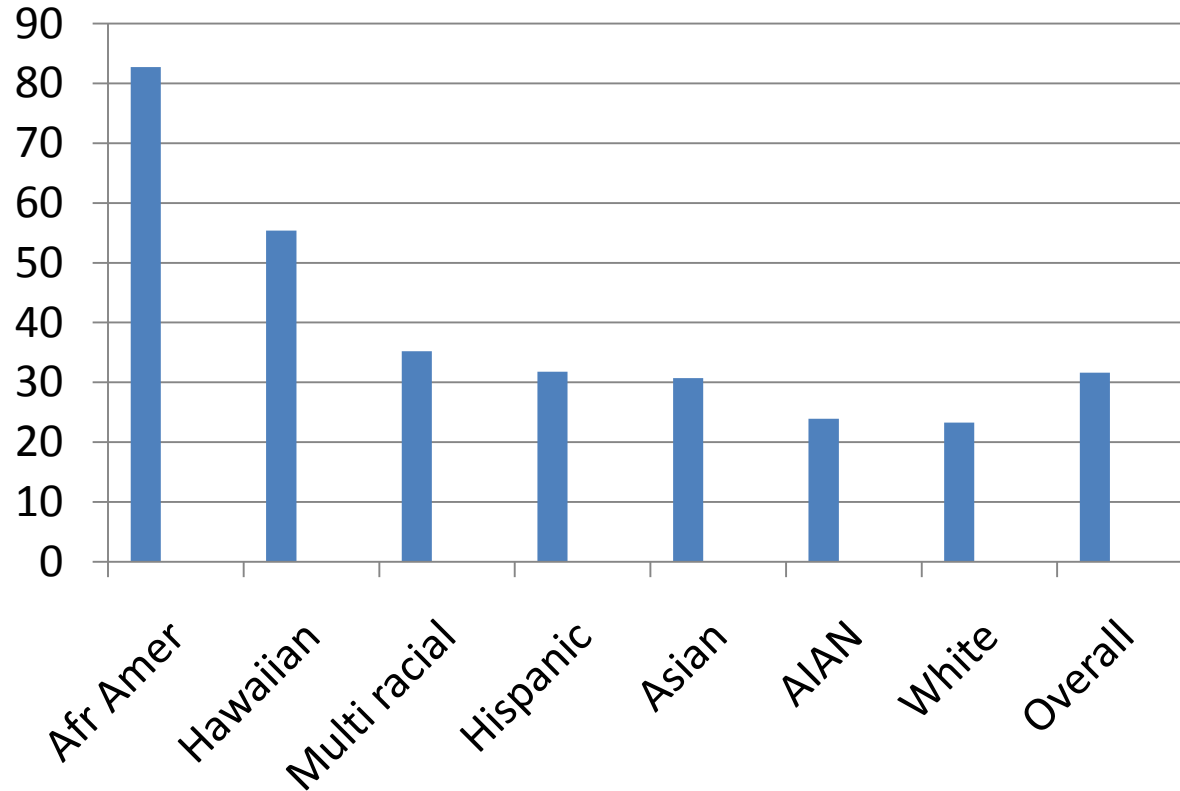
- 1.1 million underage adolescents smoked menthol cigarettes
- 18.1 million adults
- 53.2% adult white smokers; but menthol use is not evenly distributed

(NSDUH, 2004-2008)

Percent Menthol Cigarette Use among Past Month Cigarette Smokers Aged 12 - 17 Years, by Race/Ethnicity: 2004-2008 (NSDUH, 2004-2008)



Percent Menthol Cigarette Use among Past Month Cigarette Smokers Aged ≥ 18 Years, by Race/Ethnicity: 2004-2008 (NSDUH, 2004-2008)



Hawaii Youth Tobacco Survey, 2000, 2003 and 2009 (Hawaii State Department of Health, 2009)

		Middle School			High School	
	2000	2003	2009	2000	2003	2009
Cigarette Prevalence	38.4	21.1	17.2	63.3	47.8	36.9
Menthol	61.5	61.4	70.0	76.1	75.8	78.4
Brand: Kools		56.1	27.1		61.1	57.6

PMI and the Philippines

- PMI has been present in the Philippines since 1955
- In 1993 Philip Morris Philippines was established to manufacture PMI's brands in country
- Philippines: Regional hub for Southeast Asian Market

(Euromonitor Cigarette Report, 2008)

PMI: Bullish on the Philippines

- PMI in 2003 acquired four local economy cigarette brands from Sterling Tobacco Corp.: *Bowling Green, Miller, Bowling Gold and Stork*
- PMI is the market leader in the Philippines with a **95% market share**
- In the Philippines, 70% of cigarette sales are in single stick sales

(Euromonitor Cigarette Report, 2008)

Filipinos and Menthol

- Menthol cigarettes constituted 55% of the cigarette market in 2007
- Marlboro Menthol Lights; Philip Morris Menthols
- Cigarettes in the Philippines were found to contain 8% more nicotine and 76% more tar than imported brands
- (Euromonitor Cigarette Report, 2008)

Assault on Asia

- **Marlboro Intense**, concentrates the tobacco of a regular length cigarette, into a half an inch shorter rod (50 int'l and Asian Markets)
- **Marlboro Mix 9**, is a high-nicotine high-tar kretek (i.e., clove cigarette) introduced in Indonesia 2007.
- **Marlboro Filter Plus**; is currently being sold in Korea (*tobacco* in the filter of the cigarette)

(Gardiner, 2008)

Assault on Asia

- **Marlboro Wides!!** Clove flavored, marketed in Indonesia: shorter and fatter and twice the nicotine level (Gardiner, 2008)
- **Kool Boost.** Menthol produced marketed in Japan; just like Camel Crush. (Dr. Itsuro Yoshimi , 2009)

The Real Prize: China

- 350 million smokers in China
- the largest tobacco producer in the world
- China consumes about 40% of the world's cigarettes
- PMI produce the Marlboro brand at Chinese state-owned factories.

O'Connell, V. Wall Street Journal, January 29, 2008; A1; Hindo, B. Business Week, January 29, 2008.

Top Ten Reasons to Ban Menthol

- **Menthol cigarettes are starter products for Youth** (Hersey, 2004; SAMSHA, 2009)
- **Menthol cigarettes have greater addiction potential** (Ferris et al, 2004) (Okuyemi, 2003; Ahijevych, 1999)
- **Unique Sensory Stimulation**
 - “Throat grab” associated with menthol similar to that of nicotine
 - Menthol is reinforcing in and of itself

Top Ten Reasons to Ban Menthol

- **Harder to quit** (Harris et al, 2004; Pletcher et al, 2006; Okuyemi 2003, 2004, 2007; Gandhi et al, 2009)
- **Greater potential for relapse** (McCarthy et al, 1995; Okuyemi et al, 2004; Pletcher et al, 2006)
- **Predatory and Relentless Marketing Toward the Most Vulnerable Populations** (Appleyard et al, 2001; Gardiner et al, 2004; Sutton and Robinson, 2004; Yerger, 2007; Heaton, 2009)
- **Bogus Health Messages: Refreshing; Alive with Pleasure**

Top Ten Reasons to Ban Menthol

- **Menthol cigarette smokers display poorer mental health** (Webb, 2009)
- **Menthol inhibits detoxification of NNAL** (Muscat et al, 2009)
- **Menthol inhibits cotinine clearance** (Benowitz et al, 2004)

FDA: Broaden the Definition of Harm

- **Harm is not solely a chemical question**
- **Narrow definition aids the tobacco industry**
- **Tobacco Products Scientific Advisory Committee**
- **Ultimately, harm is a social justice issue that should assesses the impact on the public's health, especially those most vulnerable amongst us**

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