

Back to the Future

**Envisioning the Remarkable Impact of
the FDA Law on U.S. Tobacco
Consumption by 2015**

Stephenie Foster



Moderator:

Senior Vice President
for Government
Relations, Legacy

- Overview:
 - Speaker positions (10 minutes)
 - Moderator Q&A
 - Audience and Web Q&A
- EMAIL QUESTIONS: press@legacyforhealth.org
- Archive @ www.legacyforhealth.org

Opening Remarks:

Cheryl G. Heaton, DrPH
President and CEO,
Legacy



Quick History:

- **1960s:** 70 million smokers in the U.S.
- **1964:** U.S. Surgeon General's Report
- **1966:** Warning labels on cigarette packs
- **1980s:** "Tar Wars"
- **1998:** Master Settlement Agreement
- **2006:** U.S. DOJ vs. Tobacco Companies
- **2010:** 46 million U.S. smokers

PANELISTS

- **David A. Kessler, M.D.**, Professor of Pediatrics and Epidemiology and Biostatistics at the School of Medicine, UCSF and Former Commissioner of the Food and Drug Administration
- **Matt Myers**, President, Campaign for Tobacco Free Kids
- **John Payton**, Director-Counsel and President of the NAACP Legal Defense and Educational Fund



**President,
Campaign for
Tobacco-Free Kids**

FDA Regulation of Tobacco One Year Later:

What has been accomplished?
Where are we going?



An Unprecedented Opportunity for Progress

- To make fundamental changes
- To expand and apply our scientific knowledge
- To counter the tobacco industry

BUT TO ALSO REALIZE

- FDA regulation is not a substitute for evidence based prevention and cessation efforts
 - Tobacco excise tax Increases
 - Restrictions on secondhand smoke
 - Funding for comprehensive tobacco control
 - Mass media
 - Coverage for smoking cessation services

Key Substantive Elements

1. Require the industry to provide **information** to the Gov't that allows Gov't to better understand tobacco products and marketing, prevent industry product manipulation and better inform consumers
2. Restrict **marketing**, especially marketing that appeals to kids, misleads adults, deceptively encourages tobacco use
3. Strengthen **restrictions on sales to youth**

4. **More accurately inform consumers/Prevent tobacco industry from misleading consumers**
 - A. Improved warning Labels
 - B. More accurate testing of tar, nicotine and other harmful substances
 - C. Standards to prohibit unsubstantiated health claims
5. Regulation of the **Contents of the Product** to protect public health, not promote the tobacco industry's bottom line

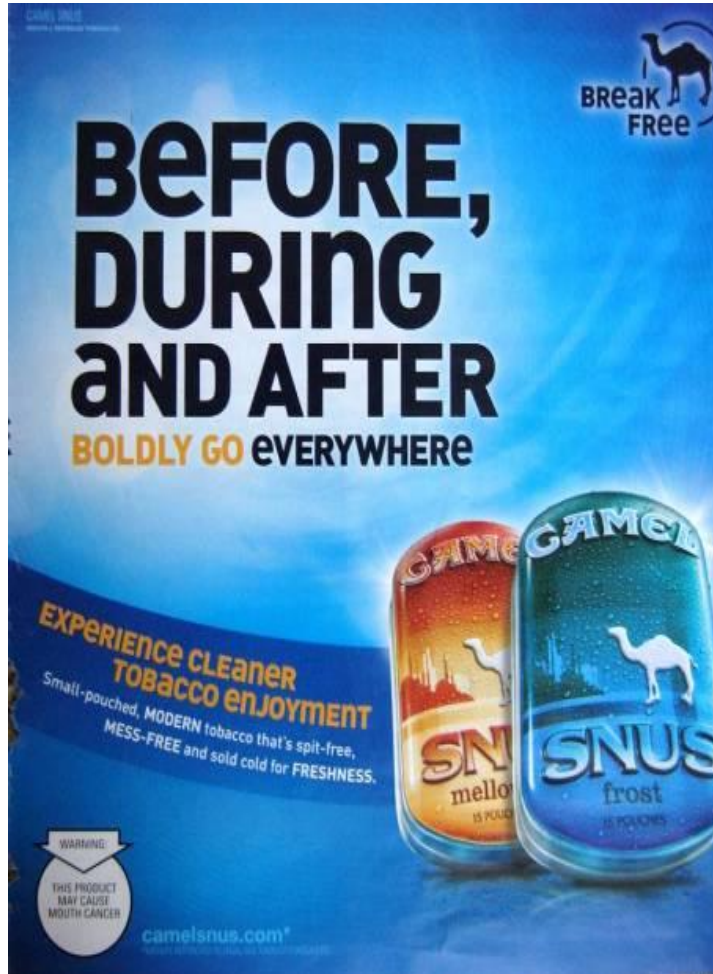
What Has FDA Done

- Ban on flavored cigarettes
- Creation of Science Advisory Board
 - Begun investigation of role of menthol
 - Begun process to ID harmful and potentially harmful constituents
 - About to begin investigation of dissolvables
- Established process for gaining information about ingredients
- Begun process of contracting with states to do youth access and marketing compliance
- Published marketing restriction rules

New Restrictions Going into Effect on June 22nd

- Prohibition of “light,” “low,” “mild,” and all similar descriptors in all advertising, labeling and marketing of cigarettes and smokeless products.
- Larger, stronger warning labels required on all smokeless tobacco packages and ads
- 1996 rule on youth access and marketing takes effect

Monitor: Smokeless Warnings on Advertising Before and After



Camel SNUS
Small-pouches, MESS-FREE

BREAK FREE

**BEFORE,
DURING
AND AFTER**

BOLDLY GO EVERYWHERE

**EXPERIENCE CLEANER
TOBACCO ENJOYMENT**
Small-pouches, MODERN tobacco that's spit-free,
MESS-FREE and sold cold for FRESHNESS.

camelsnus.com*

WARNING:
THIS PRODUCT
MAY CAUSE
MOUTH CANCER

*SEEK MEDICAL ADVICE IF YOU ARE CURRENTLY SMOKING

Camel SNUS advertisement showing two pouches (mello and frost) and the text "BEFORE, DURING AND AFTER BOLDLY GO EVERYWHERE". It includes a "BREAK FREE" logo and a warning about mouth cancer.



Camel SNUS
Small-pouches, MESS-FREE

BREAK FREE

**BEFORE,
DURING
AND AFTER**

BOLDLY GO EVERYWHERE

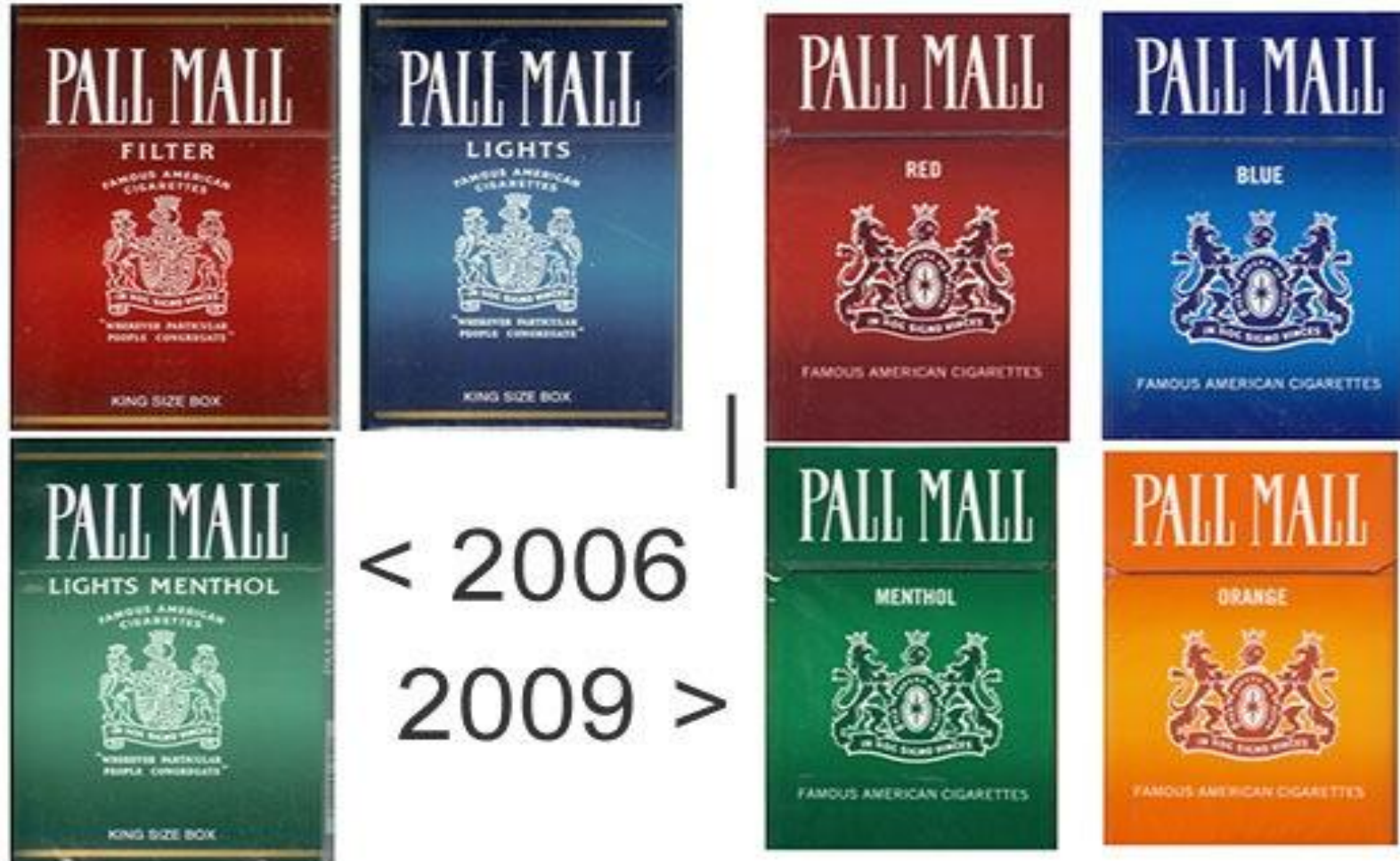
**EXPERIENCE CLEANER
TOBACCO ENJOYMENT**
Small-pouches, MODERN tobacco that's spit-free,
MESS-FREE and sold cold for FRESHNESS.

camelsnus.com*

WARNING: This product can cause
gum disease and tooth loss.

Camel SNUS advertisement showing two pouches (mello and frost) and the text "BEFORE, DURING AND AFTER BOLDLY GO EVERYWHERE". It includes a "BREAK FREE" logo and a warning about gum disease and tooth loss.

Monitor “Color Coding” of Light/Low Products



NYC Health Department Launches New TV Ads to Alert the Public to Tobacco Industry's Color Coding of Cigarette Packs

- *Campaign warns viewers that all cigarettes are hazardous, despite packaging that implies some are lighter and safer*
- *The ads advise viewers that cigarettes are deadly whatever their package color. “Don’t be fooled,” a narrator says as brightly colored packages fill the screen. “All cigarettes contain the same poisons that make you sick and kill you. The new ads can be viewed at nyc.gov/health.*



New Restrictions on Tobacco Product Sales & Marketing Going into Effect on June 22nd

- 1996 Rule
 - No cigarette or smokeless tobacco sales to minors - this is the first time these sales are prohibited by *federal law*.
 - No vending machine sales or self-service displays of cigarettes or smokeless tobacco except in adult-only facilities.
 - No sales of cigarettes in packages of fewer than 20 cigarettes.
 - No branded product tie-ins (e.g., T-shirts with brand names or images) with purchases of cigarettes or smokeless tobacco products.
 - No branded sponsorships of athletic or cultural events by cigarette or smokeless manufacturers, distributors or retailers.
 - No free samples of any tobacco products, except that limited free samples of smokeless allowed in temporary adult-only facilities in certain restricted situations.



New Restrictions on Tobacco Product Sales & Marketing Going into Effect on June 22nd

- 1996 Rule – Implementation delayed
 - New restrictions on outdoor cigarette or smokeless advertising near schools.
 - All cigarette and smokeless advertising must be black text on white background only – with all audio ads only spoken words with no sound effects or music – except in adult-only facilities and in magazines with less than 15% or fewer than 2 million youth readers. (legal challenge)

The Challenge Ahead – a Big Picture Outlook

1. Truly changing the image of tobacco products
2. Ending the information advantage of the tobacco industry
3. Ending the ability of the industry to keep people smoking through the false allure of a “safer smoke”
4. Taking control of the tobacco product to “protect public health”

Changing the Image of Tobacco Products

- Tobacco industry doesn't sell a product, it sells an image: The Marlboro Cowboy, The Virginia Slims Woman, Newport Pleasure, Camel No. 9
- It uses every available tool: The Package, Ads, Sponsorship, Product Placement, Retail Displays
- Benchmark for Success: Have FDA and others used the tools now available to ensure tobacco products are seen for what they are and not for what the tobacco industry wants us to see

- Effective, new and regularly refreshed warning labels
- Monitoring and evaluating Industry marketing and responding effectively
- Developing a strategy at the retail level
- Coordinating FDA's regulatory power with other agencies. Pairing FDA action with:
 - Effective mass media – NYC, Truth, CDC
 - Funding of state and local tobacco control efforts

Cigarette pack now



Front



Back

Cigarette pack under FDA Regulation



Front



Back

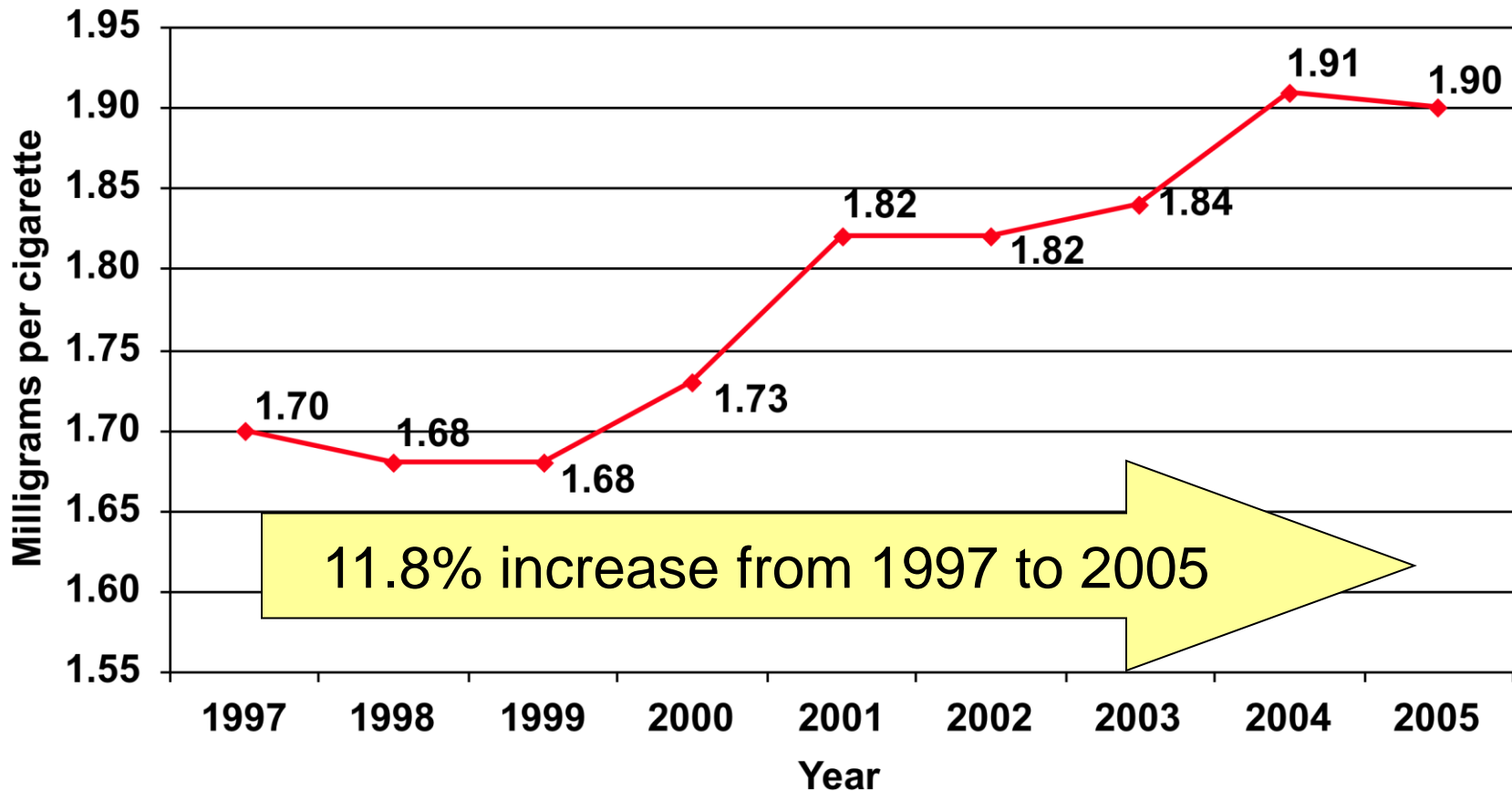


Ending the Information Advantage of the Tobacco Industry

- What is the role of industry manipulation of the product to: Initiation; youth appeal; cessation; disease risk
- What is the industry doing to tobacco products
- What does the industry know about the impact of different marketing techniques
- Benchmark of Success: Does FDA effectively gain access to the information needed to ensure that FDA can fully answer these questions in real time?

Increased Nicotine Levels in Cigarettes Average Nicotine Yields Per Cigarette 1997-2005

Harvard School of Public Health, 2006



Increase In Certain Carcinogens

- While changes in tobacco blends and types led to a **decrease** of the tar levels in smoke, these changes were accompanied by **higher** levels of the carcinogenic NNK.

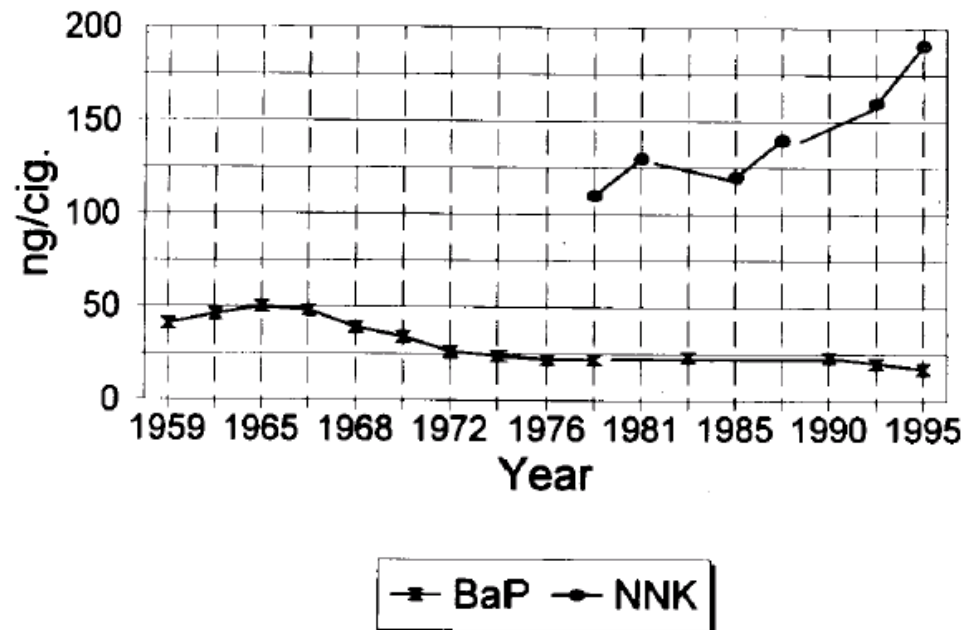


FIGURE 17. Benzo[a]pyrene and NNK in mainstream smoke of U.S. leading NF cigarette, 1959–1995 (Djordjevic et al., 1996; Hoffmann & Hoffmann, 1994).

Taking Control of the Tobacco Product to “Protect Public health”

- **Closely related to closing the information gap is the use of FDA’s authority over the product:**
 - Section 907 is often discussed in terms of reducing disease risk of products. It is also a tool to prevent the industry from doing things to the product that increase addiction and initiation and decrease cessation
- Benchmark: Has FDA implemented standards governing tobacco products that prevent the industry from manipulating their products in ways that increase tobacco use and decrease cessation as well as increase the risk of disease?

Are Cigarettes More Hazardous Than Ever?

Risk Of Getting Lung Cancer Has Increased Due To Changes In Design, New Study Suggests

April 30, 2009 | by Stephanie Condon

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Cigarettes Deadlier Than Ever?

For the past 50 years, U.S. manufacturers have been using a new process to dry tobacco. The process has led to the formation of a highly carcinogenic substance in the leaf. Mark Phillips reports. | [Share/Embed](#)

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(CBS) A new study presented today suggests that the risk of getting lung cancer from smoking has increased over time due to changes in cigarette design.

Up to one half of current lung cancer occurrence could be attributable to cigarette design, according to David Burns and Christy Anderson of the University of California at San Diego School of Medicine. Consequently, the study concludes, lung cancer rates could be reduced by up to 50 percent through more regulatory control of cigarette composition.

 [Tobacco Study Abstract](#)

Burns and Anderson presented their study today at the meeting of the Society for Research on Nicotine and Tobacco in Dublin, Ireland.

The study examined lung cancer rates as well as changes in the design and smoke composition of

Ending the Ability of the Industry to Keep People Smoking through the False Allure of a “Safer Smoke”

- For 50 years the industry has kept people smoking by promising safer cigarettes –
 - Micronite Filter, Trionic Filter
 - Light, Low Tar, Reduced Carcinogens
- To date – No cigarette has been proven to actually reduce the risk of disease
- Benchmark: Has FDA effectively ended the greatest consumer fraud of all time and its new permutations

Sec 915 – Product Testing Sec 206 – Replacing FTC Test Method

- Authorized to promulgate regulations that require new testing in a manner to be set by FDA.
- The testing goes beyond tar and nicotine to include tobacco product constituents, ingredients, and additives, including smoke constituents.

Prohibiting Unproven Health Claims

Section 911

- Prohibit claims until science is adequate to reach meaningful conclusions
- Does not prohibit introduction of potentially less hazardous products
- A rigorous scientific standard to avoid mistakes but that doesn't discourage scientific innovation
- Post-market surveillance

The Goal: If consumers understand the real choice – more will quit and none will be fooled

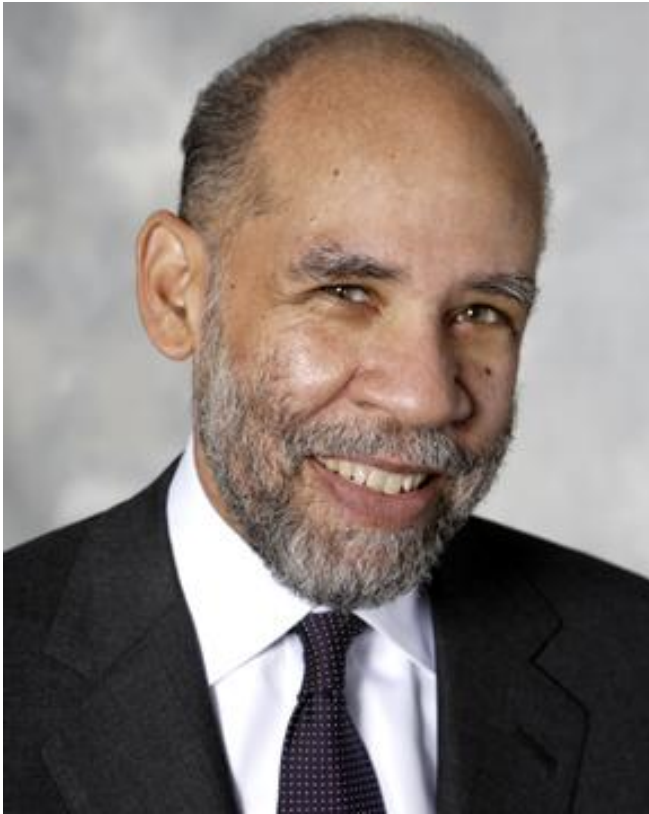
- The potential for change is great – but it must be seized.
 - FDA has been given enormous authority – covering every aspect that has contributed to the tobacco epidemic – If properly used
 - FDA’s authority must be used in conjunction with other proven tobacco prevention and cessation tools
 - To succeed, we need to have clear goals

**Former Commissioner of
the Food and Drug
Administration**

**Professor of Pediatrics
and Epidemiology and
Biostatistics, University
of California, San
Francisco**



John Payton



**President and
Director-Counsel
NAACP Legal Defense
and Educational
Fund, Inc.**

Moderator Q&A

email: press@legacyforhealth.org





Audience Questions



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