

# FDA's Nutrition Innovation Strategy

**Douglas Stearn**

Deputy Director for Regulatory Affairs  
Center for Food Safety and Applied Nutrition  
FDLI Food Advertising Conference  
September 26, 2018

# FDA Food Responsibilities

- 20¢ of every consumer dollar in the US spent on FDA-regulated products
- FDA regulates safety & labeling of 80% of all food consumed in the United States
  - Ensure that consumers are provided with accurate and useful information in food labeling
  - Encourage food product reformulation to create healthier products
- Close collaboration with CDC, NIH, USDA and other federal partners



of food supply  
regulated by FDA



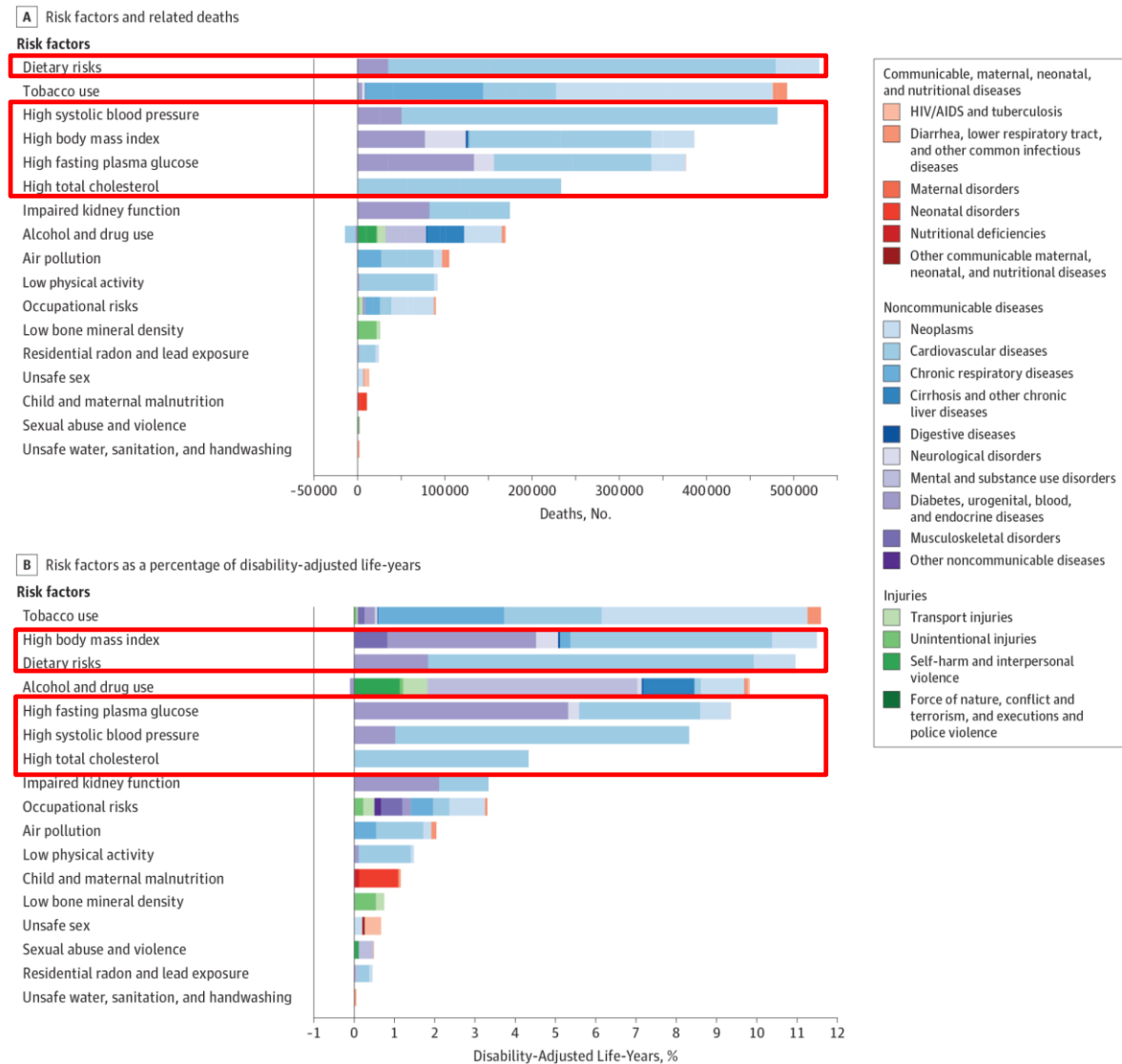
**1** in **3** U.S. adults have high blood pressure

Almost **40%** of U.S. adults are obese

Almost **1** in **5** of U.S. children and adolescents are obese



# Number of Deaths and Percentage of Disability-Adjusted Life-Years Related to the 17 Leading Risk Factors in the United States, 2016



Source:  
**The State of US Health, 1990-2016 Burden of Diseases, Injuries, and Risk Factors Among US States** JAMA.  
 2018;319(14):1444-1472. doi:10.1001/jama.2018.0158

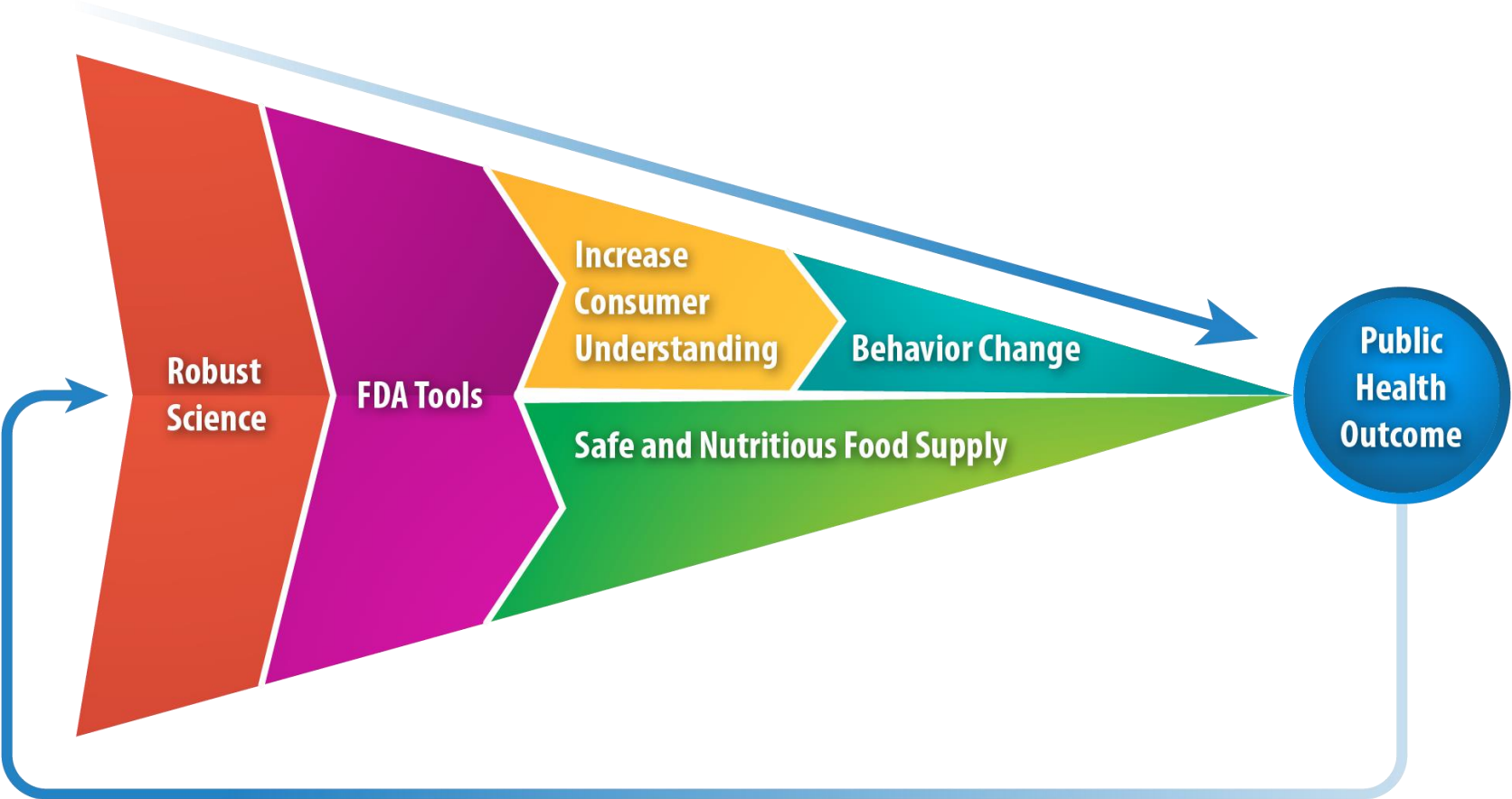
# Current Eating Patterns Compared to Recommendations



**Note:** The center (0) line is the goal or limit. For most, those represented by the orange sections of the bars, shifting toward the center line will improve their eating pattern.

**Data Source:** What We Eat in America, NHANES 2007-2010 for average intakes by age-sex group. Healthy U.S.-Style Food Patterns, which vary based on age, sex, and activity level, for recommended intakes and limits.

# Conceptual Framework FDA & Nutrition



## Robust Science



- Etiologic Research
- Behavioral Research
- Surveillance
  - Nutritional status
  - Population health
  - Food supply

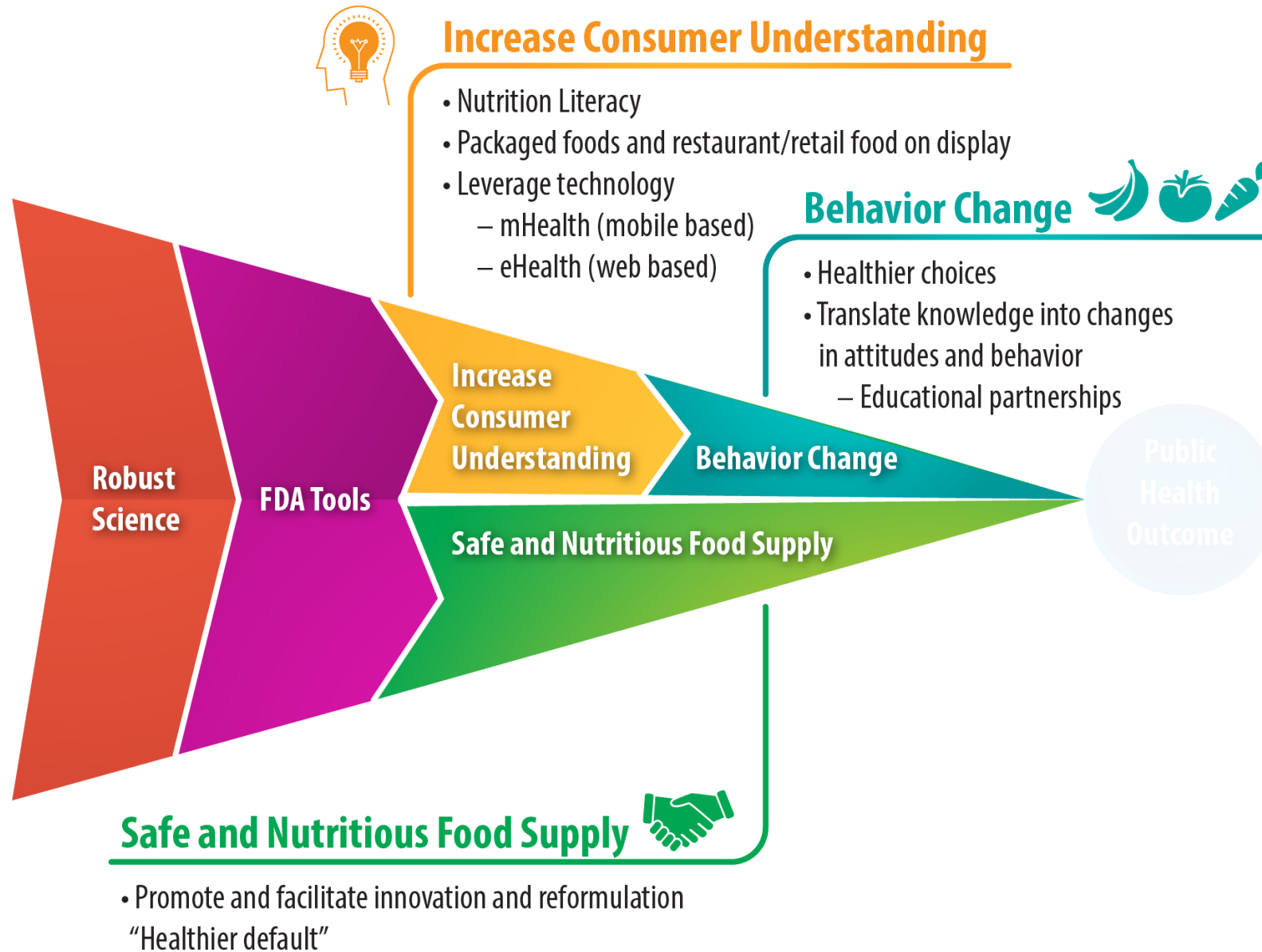




## FDA Tools



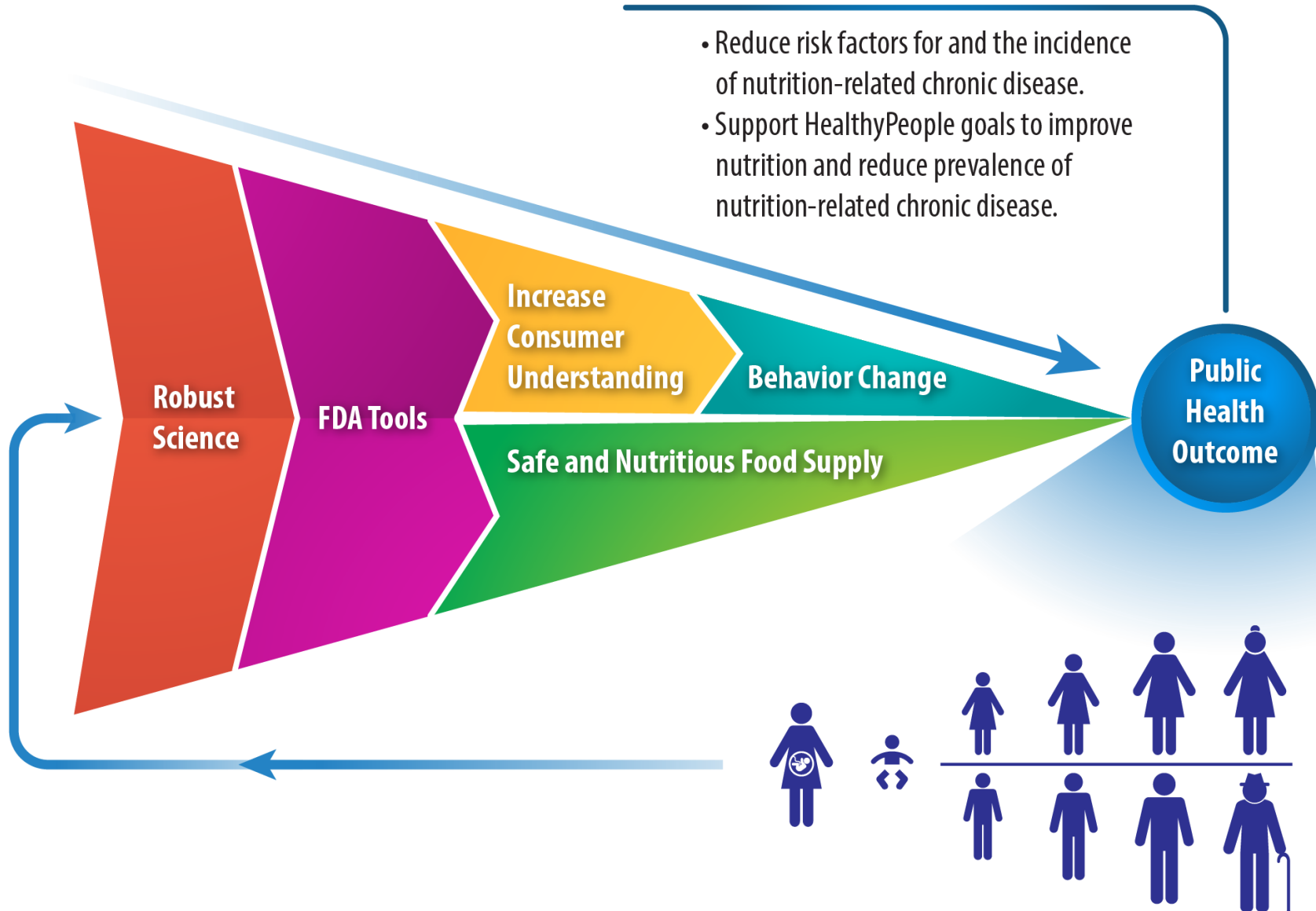






## Public Health Outcome

- Reduce risk factors for and the incidence of nutrition-related chronic disease.
- Support HealthyPeople goals to improve nutrition and reduce prevalence of nutrition-related chronic disease.



# Nutrition Innovation Strategy



# FDA Nutrition Innovation Strategy

“Improvements in diet and nutrition offer us one of our greatest opportunities to have a profound and generational impact on human health....The public health gains of such efforts would almost certainly dwarf any single medical innovation or intervention we could discover.”

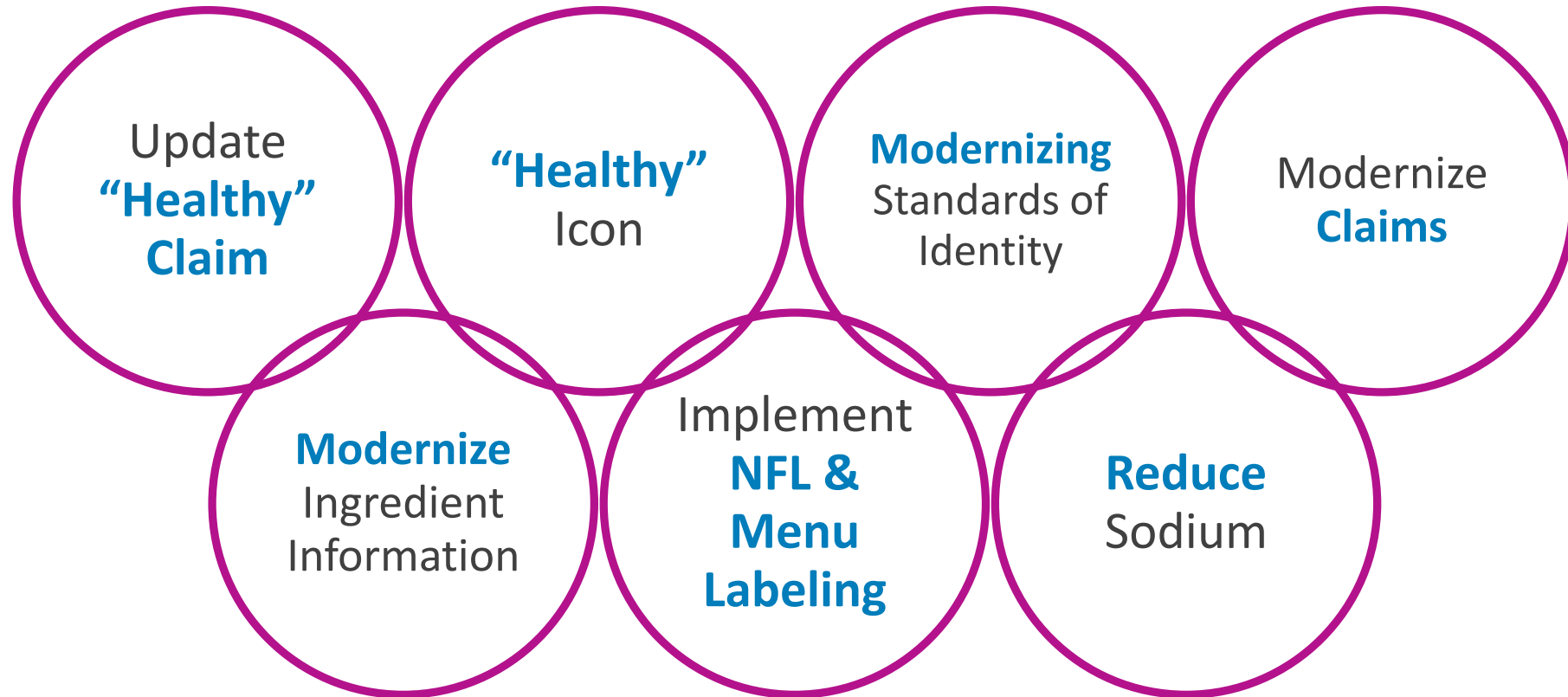
Scott Gottlieb, M.D.  
National Food Policy Conference  
March 29, 2018

# FDA Nutrition Innovation Strategy

## Goals:

- (1) Empower consumers with information to help them make more informed dietary choices; and
- (2) Foster and support innovation already underway in the food industry that will allow industry to compete on the basis of healthful attributes.

# Nutrition Innovation Strategy Initiatives



# Modernizing Claims

- Claims on food and beverage products act as quick signals for consumers about the nutritional benefits of those products, and they can encourage the industry to reformulate products to improve their healthy qualities
- The nutrient content claim “healthy” is one claim that is ready for a change to be more consistent with current science
- Along with updating the definition of the claim “healthy” we are exploring ways to depict “healthy” on the package so consumers can easily find it

# Qualified Health Claim: Early Introduction of Peanuts to Certain High-risk Infants may Reduce Risk of Peanut Allergy



## Addendum Guidelines for the Prevention of Peanut Allergy in the United States

Report of the NIAID-Sponsored Expert Panel



### News & Events

Home > News & Events > Newsroom > Press Announcements

### FDA Statement

**Statement from FDA Commissioner Scott Gottlieb, M.D., on a new qualified health claim advising that early introduction of peanuts to certain high-risk infants may reduce risk of peanut allergy**

[SHARE](#) [TWEET](#) [LINKEDIN](#) [PIN IT](#) [EMAIL](#) [PRINT](#)



FDA OKs new peanut allergy food labels



## Modernizing Claims – cont.

- FDA is also interested in exploring claims for products that offer food groups for which American diets typically fall short of recommendations
  - Examples include whole grains, low-fat dairy, fruits and vegetables, and healthy oils
- Availability of information about nutrients – both those we need to limit (e.g., added sugars), and those that consumers aren't getting enough of (e.g., potassium), remains a core aspect of FDA's role and nutrition strategy

# Modernizing Ingredient Information

- FDA plans to re-evaluate the ingredient information on food packages to see what changes could make it more consumer-friendly
  - E.g., Making information more readable and understandable by changing font or declaring ingredients by names in common usage
- Combining food claims and making ingredient information on labels easier to decipher can allow consumers to choose healthy diets, while staying within caloric guidelines

# Modernizing Standards of Identity

- Standards of identity establish requirements related to the content and production of certain food products.
- FDA will take a fresh look at existing standards of identity in light of marketing trends and the latest nutritional science.
- The goal is to maintain the basic nature and nutritional integrity of products while allowing industry flexibility for innovation to produce more healthful foods.

# Implementing Menu Labeling

- May 7, 2018: Menu labeling compliance date; FDA released final guidance that provides flexibility on how covered establishments can provide calorie information in ways that meet various business models.
- The new measures will, for the first time, create a national and uniform standard for the disclosure of calorie information on menus at chain restaurants and other retail establishments.



**Example of declaring calories for multiple items on a self-service salad bar or a single sign attached to the sneeze guard**










**Example of declaring calories for self-service foods on individual signs using gel clings on the sneeze guard**

7/7/17-B


# CREATE YOUR OWN PIZZA CALORIES ARE LISTED PER SLICE

## CHOOSE YOUR SIZE & CRUST


 \$9.99	 \$11.99	 \$13.99	 \$15.99
---	---	---	---



PAN



THIN & CRISPY




ORIGINAL

### CHEESE PIZZA

ORIGINAL (200-240 Cal.), THIN & CRISPY (150-190 Cal.), PAN (260-300 Cal.), GLUTEN FREE† (140 Cal.)





†ONLY AVAILABLE IN SMALL

## CHOOSE YOUR SAUCE\*



TOMATO SAUCE (10 Cal.), SPICY MARINARA (10 Cal.), WHITE GARLIC SAUCE (30-50 CAL.), BBQ (10-20 Cal.)

## CHOOSE YOUR TOPPINGS\*

 \$1.00	 \$1.50	 \$2.00	 \$2.25
--	--	--	--

### MEATS

BACON (45-60 Cal.), BEEF (40-45 Cal.), CHICKEN (15-20 Cal.), HAM (10-15 Cal.), PEPPERONI (25-35 Cal.), SALAMI (25-30 Cal.), ITALIAN SAUSAGE (40-50 Cal.)

### VEGGIES

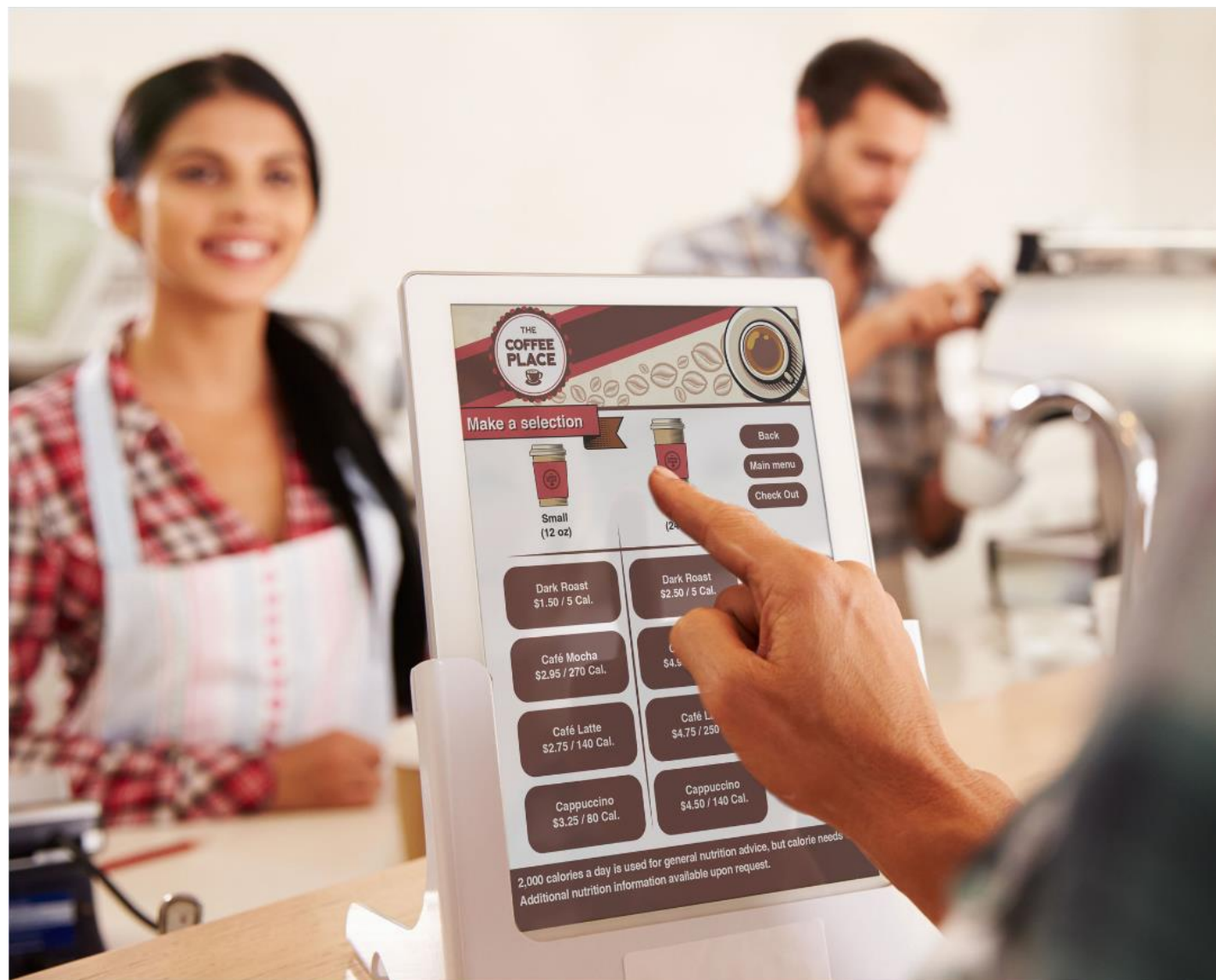
BANANA PEPPERS (0-5 Cal.), GREEN PEPPERS (0 Cal.), JALAPENOS (0-5 Cal.), FRESH MUSHROOMS (5 Cal.), BLACK OLIVES (10-15 Cal.), FRESH ONIONS (0-5 Cal.), PINEAPPLE (10 Cal.), ROASTED RED PEPPERS (0 Cal.), FRESH BABY SPINACH (0 Cal.), TOMATOES (5 Cal.)

2,000 CALORIES A DAY IS USED FOR GENERAL NUTRITION ADVICE, BUT CALORIE NEEDS VARY  
 ADDITIONAL NUTRITION INFORMATION AVAILABLE UPON REQUEST

\*ADDED CALORIES FOR 1 TOPPING PIZZA

**Example of declaring calories per slice for a build-your-own pizza using a string format**





**Example of an in-store tablet where a customer can place an order and calories are declared before purchase**



# Menu Labeling – Additional Nutrition Information

- A statement is required on menus and menu boards declaring “additional nutrition information available upon request.”
- The following written nutrition information is required to be available to consumers upon their request:

Total calories	Sodium
Total fat	Total carbohydrates
Saturated fat	Fiber
<i>Trans</i> fat	Sugars
Cholesterol	Protein

- The statement regarding the availability of the additional written nutrition information must be posted prominently and in a clear and conspicuous manner.

# Implementing Nutrition Facts Label

- May 4, 2018: FDA published a final rule extending compliance date
  - Jan 1, 2020 for manufacturers with annual food sales at or above \$10 million. Jan 1, 2021 for all others
- Many manufacturers have already started using the new labels
  - Additional time helpful for manufacturers using isolated or synthetic fibers
  - Additional time also allows time for USDA to issue its rule on disclosure of genetically engineered ingredients
- March 1, 2018: FDA issued guidance on issues such as fiber, added sugars, and serving size declarations
- FDA has announced the launch of a major educational campaign surrounding the new nutrition information consumers will be seeing in the marketplace

# SIDE-BY-SIDE COMPARISON

## Original Label

### Nutrition Facts

Serving Size 2/3 cup (55g)  
Servings Per Container About 8

#### Amount Per Serving

**Calories** 230      Calories from Fat 72

**% Daily Value\***

**Total Fat** 8g      **12%**

Saturated Fat 1g      **5%**

Trans Fat 0g

**Cholesterol** 0mg      **0%**

**Sodium** 160mg      **7%**

**Total Carbohydrate** 37g      **12%**

Dietary Fiber 4g      **16%**

Sugars 1g

**Protein** 3g

Vitamin A      10%

Vitamin C      8%

Calcium      20%

Iron      45%

\* Percent Daily Values are based on a 2,000 calorie diet.  
Your daily value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

## New Label

### Nutrition Facts

8 servings per container  
**Serving size** 2/3 cup (55g)

#### Amount per serving

**Calories** **230**

**% Daily Value\***

**Total Fat** 8g      **10%**

Saturated Fat 1g      **5%**

Trans Fat 0g

**Cholesterol** 0mg      **0%**

**Sodium** 160mg      **7%**

**Total Carbohydrate** 37g      **13%**

Dietary Fiber 4g      **14%**

Total Sugars 12g

Includes 10g Added Sugars      **20%**

**Protein** 3g

Vitamin D 2mcg      10%

Calcium 260mg      20%

Iron 8mg      45%

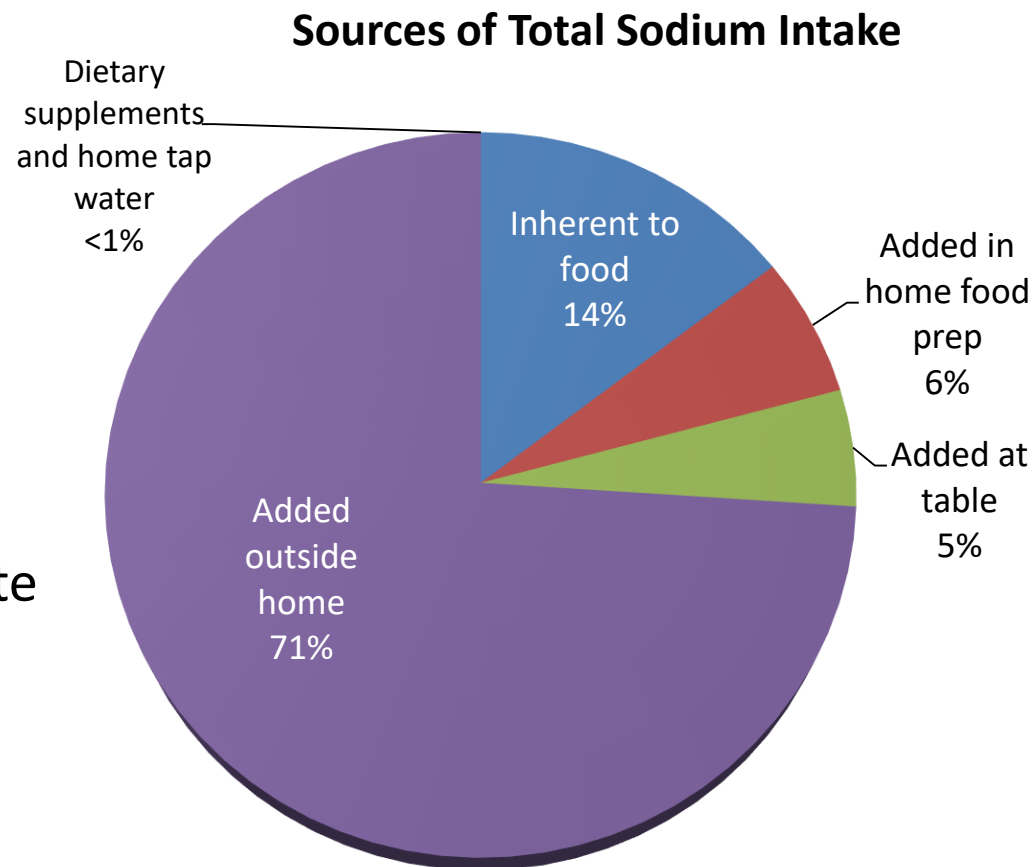
Potassium 235mg      6%

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

# Reducing Sodium

## Why are Targets Needed?

- Most sodium comes from salt added to processed and restaurant foods
- It is difficult to meet recommended sodium intake with current food supply
- Overall sodium content of the food supply remains high, despite industry efforts
- Variability in sodium across similar foods in the food supply shows that reductions are possible



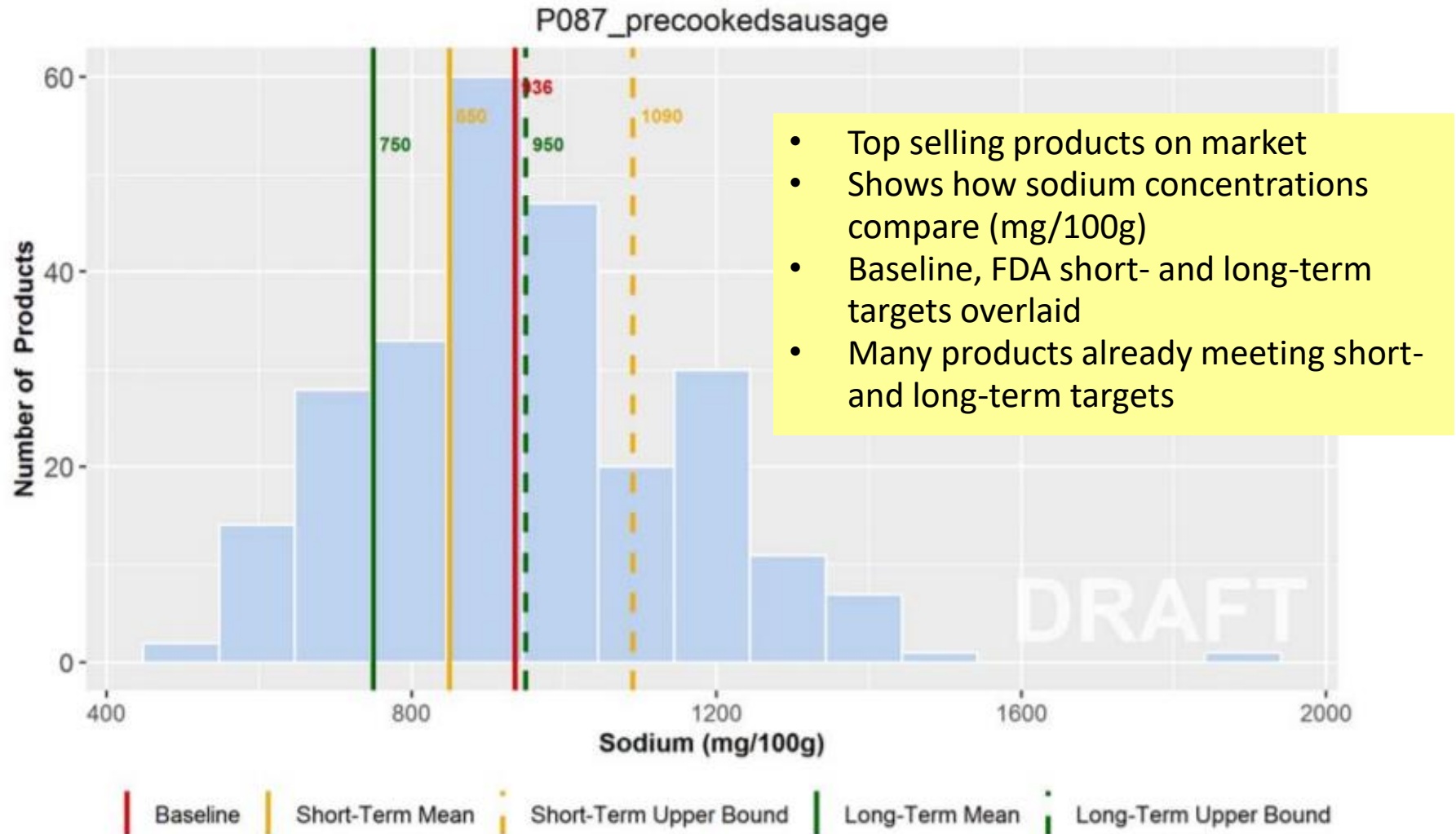
Harnack et al., Circulation 2017

# Reducing Sodium - Overview of FDA Approach



- Draft, voluntary guidance on sodium reduction targets
  - Gradual approach
  - Targets for 150 categories of food
  - Applies to food manufacturers, restaurants and food service operations
  
- Draft targets serve as a basis for continued dialogue

# Sample Category: Precooked Sausage



Note: Data on the number of products was obtained from Nielsen. Sodium concentration values were calculated from sodium values on nutrition labels obtained from Gladson and Mintel.

# Public Meeting

## July 26, 2018

909

people attended



# Next Steps

- Written Comments on the NIS can be submitted to the public docket [FDA-2018-N-2381] by October 11, 2018
- Access the docket at: <https://www.regulations.gov>
- All the initiatives have their own timelines
- The initiatives have different goals and will produce different deliverables such as requests for information, guidance documents, and/or rules based on their goals
- We are committed to extensive stakeholder engagement to help inform how best to promote public health in the evolving food and beverage marketplace



# Conclusion

- Consumers want healthier options.
- America's food industry is ripe for innovation.
- Food producers want to develop healthy options and make claims about these attributes.
- FDA supports these innovations.
- Science-based regulations and transparent labels will make it easier for consumers to understand the impact that day-to-day food choices have on their long-term health. They also make it practical for producers to compete on these features.

