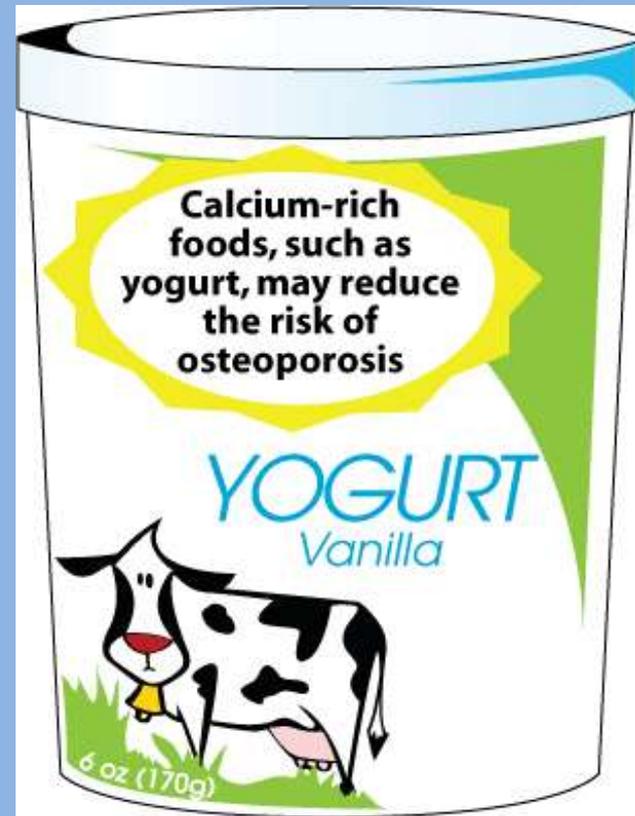
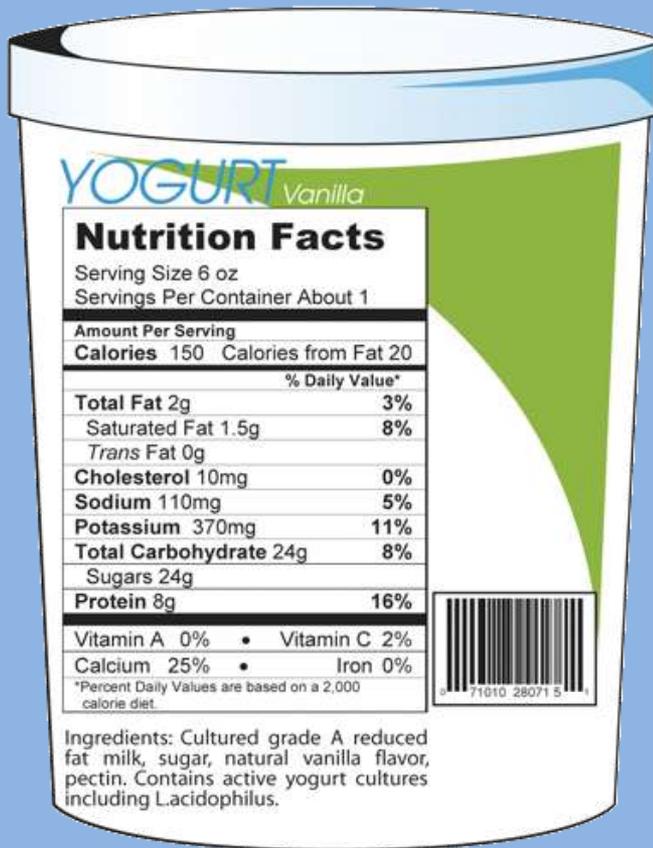




Nutrition labeling: regulatory tools for promoting public health

Carolyn Chung, PhD
**Center for Food Safety and Applied
Nutrition**
Office of Nutrition, Labeling & Dietary
Supplements
Nutrition Program Staff

The Nutrition Facts Label and Health Claims





Nutrition Labeling and Education Act of 1990*

- Requires nutrition labeling on most food packages and nutrients
- Nutrients presented in context of a daily diet
- Help consumers maintain healthy dietary practices
- Encourage innovations in food products

*Amended the 1938 Federal Food, Drug and Cosmetic Act (FFDCA)

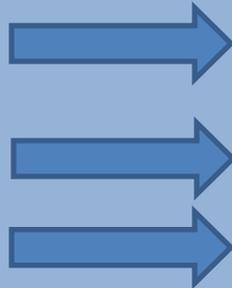


Nutrition Facts Label and NCD risk

- Well-established scientific evidence linking nutrient & chronic disease risk, a health-related condition, or physiological endpoint
- Nutrients for which the RDA* or AI* are based on chronic disease risk, a health-related condition, or physiological endpoint

*RDA= Recommended Dietary Allowance; AI = Adequate Intake

Examples of nutrients and NCD risk



Nutrition Facts			
Serving Size 1/2 cup (about 82g)			
Servings Per Container 8			
Amount Per Serving			
Calories 200		Calories from Fat 130	
<hr/>			
% Daily Value*			
Total Fat 14g			22%
Saturated Fat 9g			45%
Trans Fat 0g			
Cholesterol 55mg			18%
Sodium 40mg			2%
Total Carbohydrate 17g			6%
Dietary Fiber 1g			4%
Sugars 14g			
Protein 3g			
<hr/>			
Vitamin A 10%		• Vitamin C 0%	
Calcium 10%		• Iron 6%	
*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300 mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g
Calories per gram:			
	Fat 9	• Carbohydrate 4	• Protein 4



Elements of a health claim

- Causal relationship between a *substance* and a *disease or health-related condition for the general U.S. population or subpopulation* (e.g., women, elderly)
- Ability to reduce the risk of disease

Selected Health Claims

AUTHORIZED

- Calcium, Vitamin D and osteoporosis
- Dietary saturated fat and cholesterol and heart disease
- Fruits, vegetables and grain products (soluble fiber) and heart disease

QUALIFIED

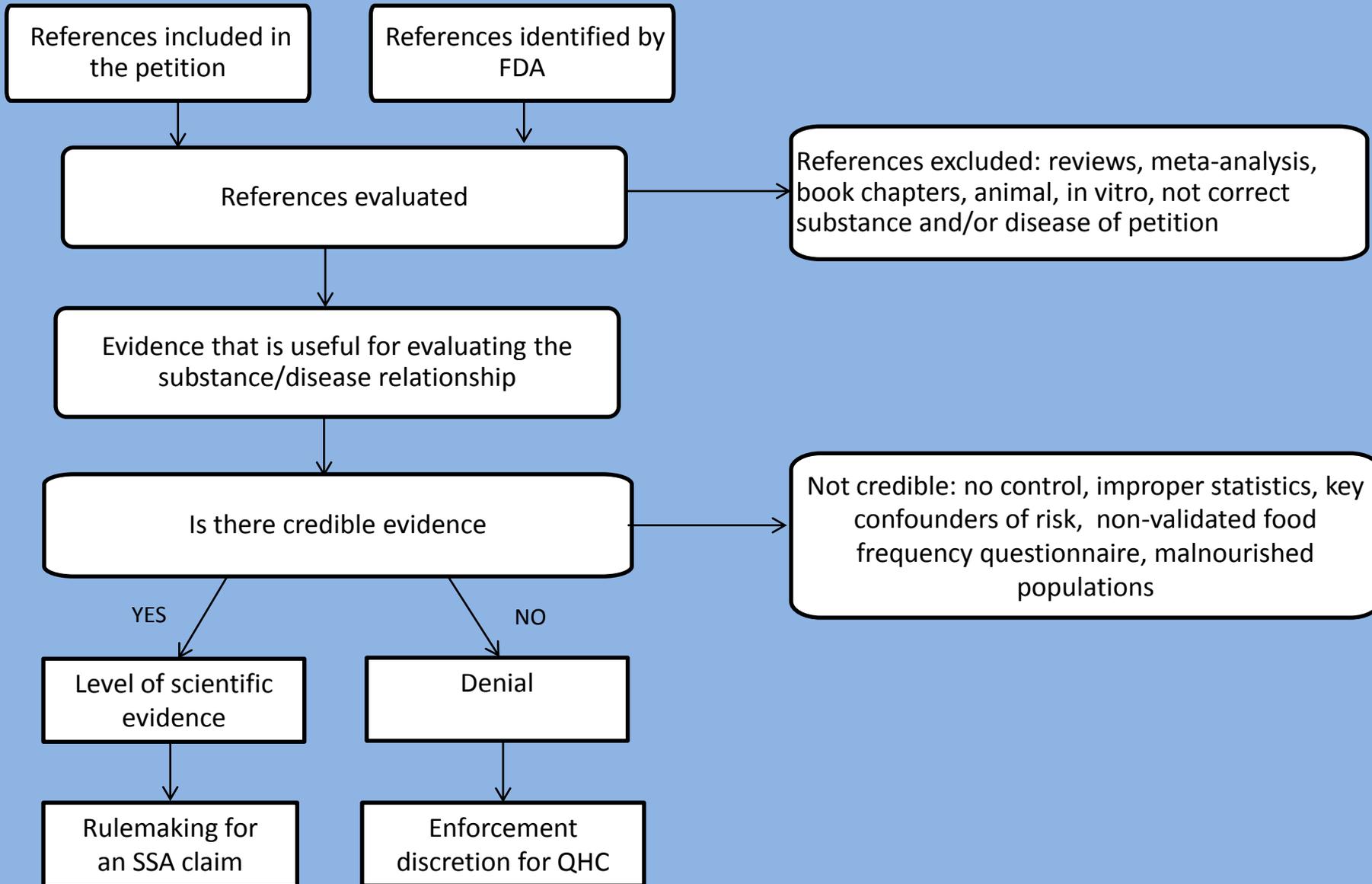
- Omega 3 fatty acids (EPA/DHA) and heart disease
- Walnuts and heart disease
- Tomato/lycopene and prostate cancer



FDA's evidence based review system for the scientific review of health claims

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm>

Evidence-based review of health claims





Some NCD risks considered in FDA regs

Nutrition Facts Label	NCD risk considered
Sat fat, trans fat, cholesterol	Coronary heart disease
Sodium	High blood pressure
Dietary fiber	Coronary heart disease
Health Claims	NCD risk considered
Soluble fiber	Coronary heart disease
Calcium, Vitamin D	Osteoporosis
Potassium	High blood pressure and stroke



Summary

- NLEA authorized FDA to implement mandatory food labeling
- The Nutrition Facts label informs consumers about nutrients with roles in NDC risk (e.g., heart disease, high blood pressure)
- Health claims are FDA approved statements that communicate information about nutrients and reduced risk for disease (e.g., heart disease)

Labeling helps us make healthy choices



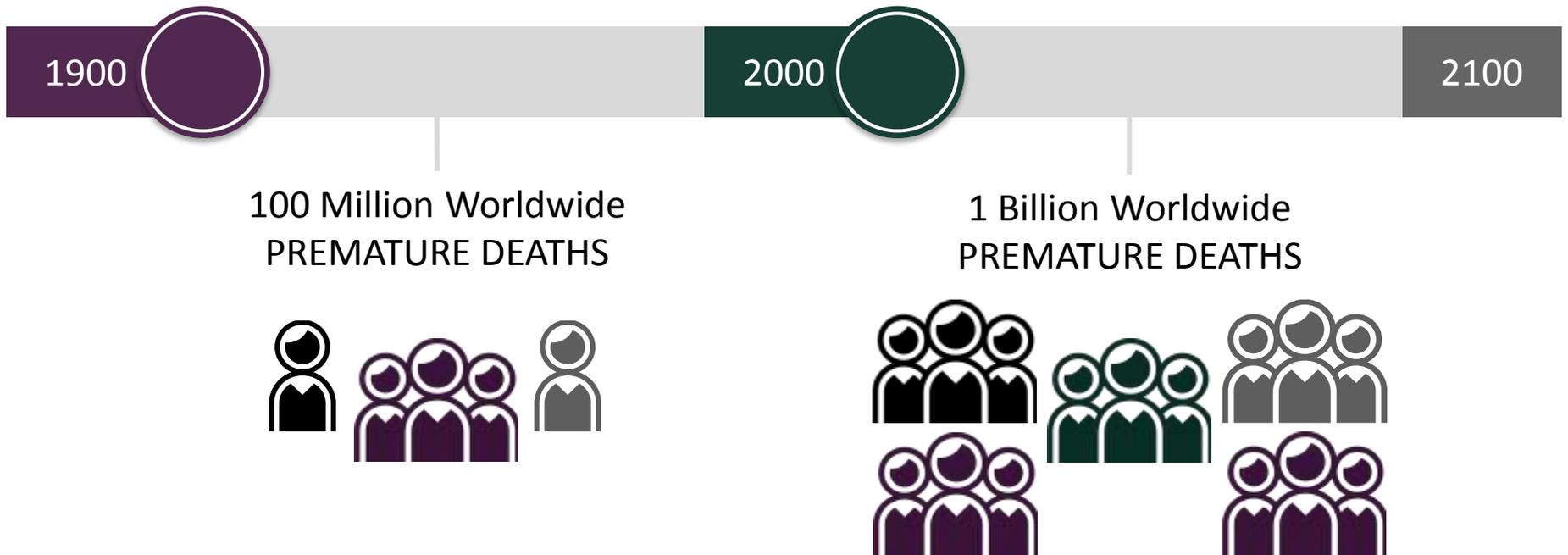
FDA's Center for Tobacco Products: The Regulation of Tobacco Products to Reduce the Burden of NCDs



Presented by
Caitlin Addorisio, JD
Office of the Center Director

The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy.

FIGHTING AN UPHILL BATTLE AGAINST DISEASE AND DEATH



IMPLEMENTING THE TOBACCO CONTROL ACT

CTP has authority to regulate tobacco products intended for human consumption to reduce harm across the population

- Regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless
- Assert jurisdiction over other products that meet the definition of a tobacco product, including e-cigarettes, cigars, and hookah



FULFILLING PROVISIONS OF THE LAW

CTP specific authorities include:

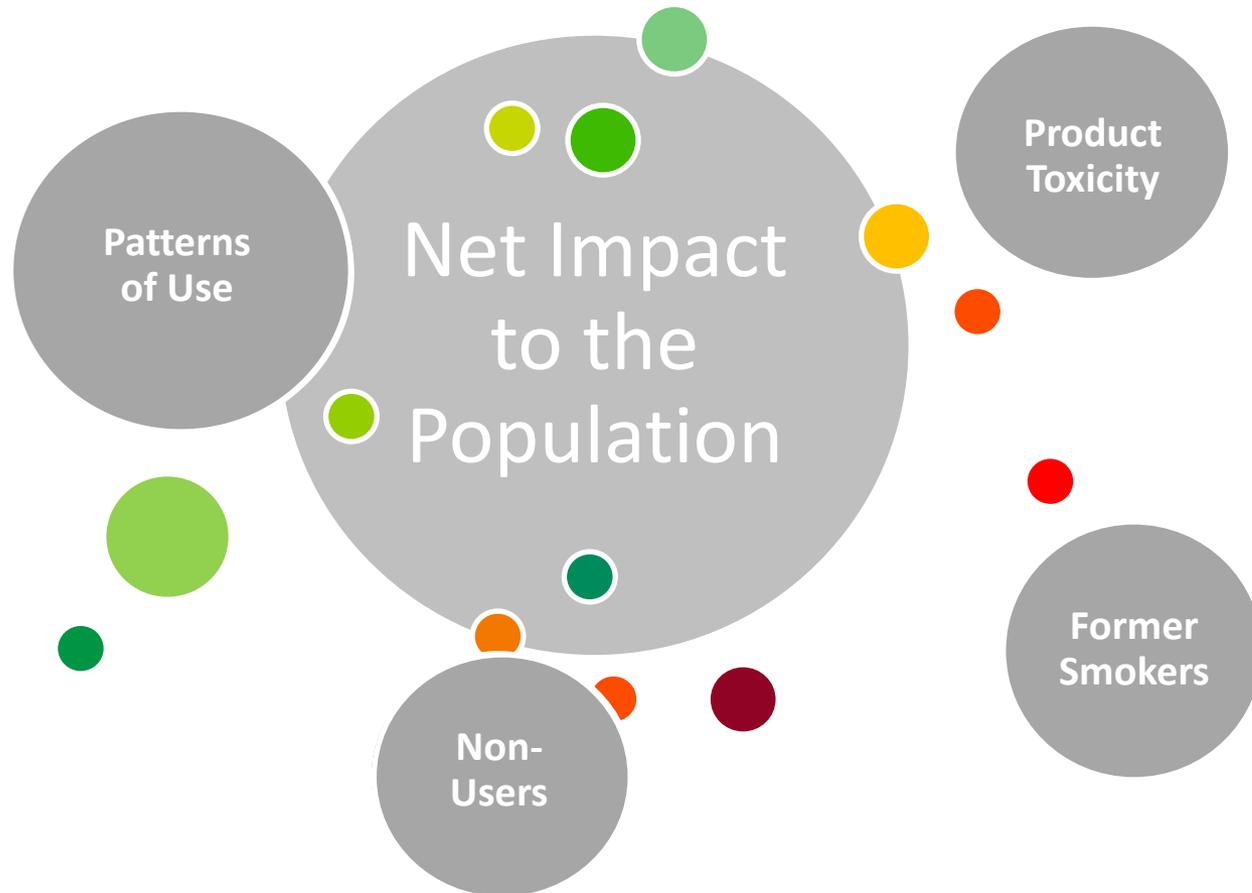
- Require tobacco manufacturers to register with the FDA
- Require listing of products and ingredients
- Require reporting levels of harmful constituents (HPHC)
- Establish tobacco product standards
- Establish limits on sale and distribution of tobacco products
- Require pre-market review for new and modified risk tobacco products (MRTPs) to protect the public health
- Require health warnings on labels and in advertising
- Establish limits on advertising and promotion of products

ACTING TO IMPROVE PUBLIC HEALTH

- Prevent youth tobacco initiation
- Encourage adults who use tobacco to quit
- Reduce product harms and addictiveness



ASSESSING OVERALL IMPACT TO PUBLIC HEALTH



PURSUING STRATEGIC PRIORITIES

- Product Standards
- Comprehensive FDA Nicotine Regulatory Policy
- Pre & Post-Market Controls: Regulations & Product Reviews
- Compliance and Enforcement
- Public Education



IMPLEMENTING ONE OF THE LAW'S MOST POWERFUL TOOLS

- Advancing a product standard strategy that yields strong standards to improve public health and that can withstand legal challenge
- Exploring potential standards for:
 - Addictiveness
 - Toxicity
 - Appeal



LOOKING AT NICOTINE DIFFERENTLY

- Establish an integrated, FDA-wide policy on nicotine-containing products that is public-health based
- Implications for tobacco, drug, and device regulatory policy



PROTECTING CONSUMERS



As the regulatory gatekeeper, CTP now stands between tobacco products and consumers

ENFORCING THE LAW

- Inspect, investigate, monitor and review activities
- Initiate appropriate enforcement actions that are supported by evidence
 - Develop and document sufficient evidence to support enforcement actions for violations of the law
 - Expand state inspection program to remaining states and territories
 - Plan for implementation of compliance activities for newly deemed products
 - Implement compliance inspection, education, and enforcement activities on tribal lands

EDUCATING AT RISK AUDIENCES ON THE DANGERS



**10
Million**



**General “At Risk” Market
Multicultural
Rural
American Indian/
Alaska Native
LGBT**

Prevention



**Investing in
our Future**

