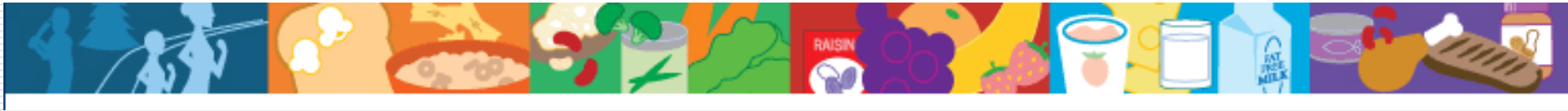




What the Heck Can I Eat?

How Confusing Health Claims and Bias in Nutrition
Research Affect One's Diet

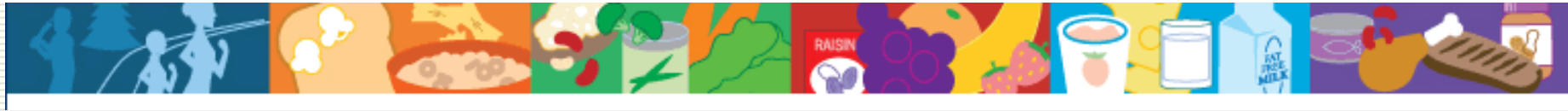
Chris Solga
May 14, 2008



Background

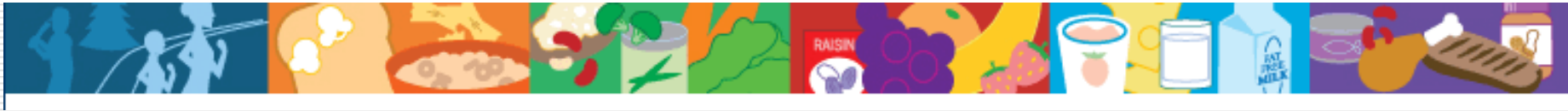
- Why did I want to research this topic?
 - Interest in nutrition
 - Sister was diagnosed with thyroid cancer





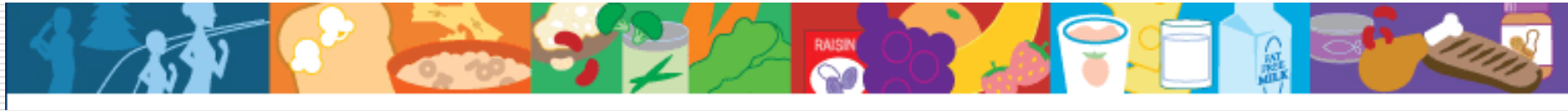
Overview

- How have the requirements for health claims changed?
 - Who can petition the FDA?
 - How do health claims get approved by the FDA?
 - How can health claims be modified to maximize their benefits?
-



Changing Requirements

- ❑ The Nutrition Labeling and Education Act (NLEA) of 1990
 - Evidence supporting the claim
 - Significant scientific agreement (SSA) among qualified experts
 - Not misleading
-



Changing Requirements

- Dietary Supplement Health Education Act of 1994
 - Structure/function claims
 - Calcium builds strong bones
 - FDA Modernization Act of 1997
 - Claims based on authoritative statements by scientific bodies
-



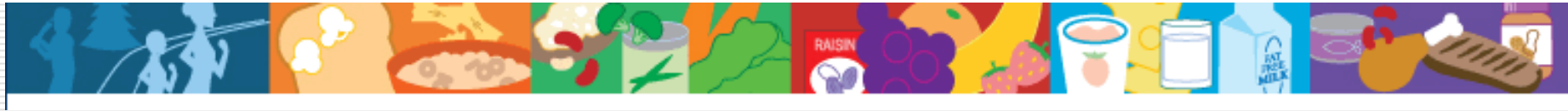
Changing Requirements

Pearson v Shalala

- District Court required FDA to permit health claims that don't meet SSA requirements, as long as they have a disclaimer

Whitaker v Thompson

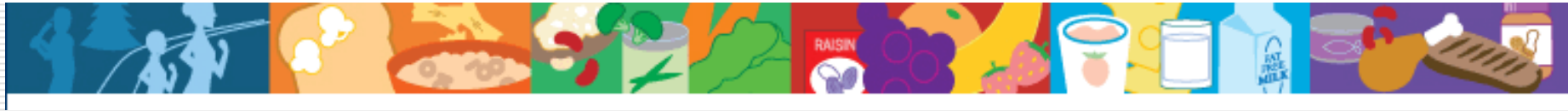
- FDA required to approve health claims in which there is credible, but inconclusive evidence
-



Types of Health Claims

- ❑ Significant Scientific Agreement or Unqualified Health Claims
 - Meet the NLEA standards

 - ❑ Qualified Health Claims
 - Claims that don't meet SSA requirement, aren't misleading, and are qualified
-



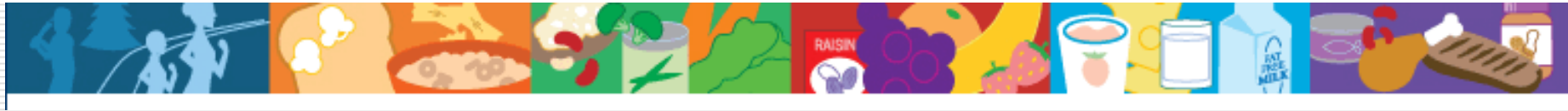
Types of Health Claims

SSA

- "3 grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease."

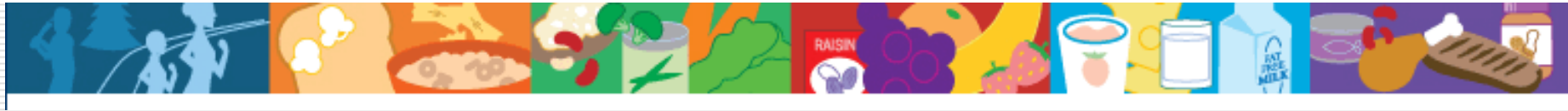
Qualified Health Claim

- "Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts...as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease."
-



Petitioning Health Claims

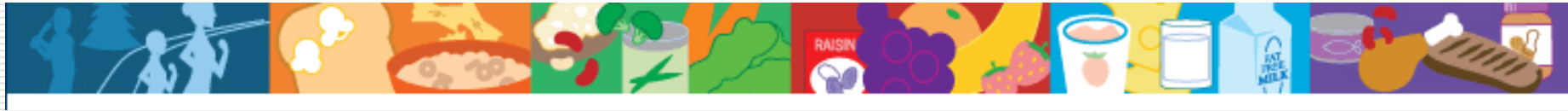
- "any interested person"
 - Nonclinical studies may be included in the petition
 - Statement verifying that the study has been conducted in compliance with good laboratory regulations
 - Statement explaining why the study was not conducted in compliance with regulations
-



Petitioning Health Claims

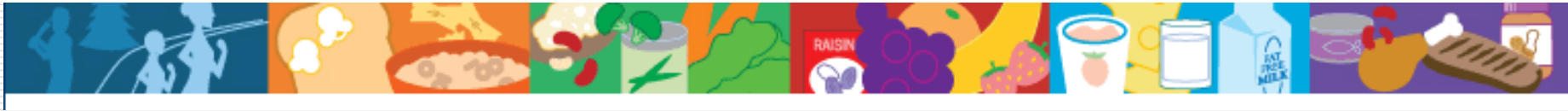
- The petition is filed within 100 days of its reception

 - FDA conducts a comprehensive review of the petition for, at the most, 90 days
-



Soy/Heart Health Claim

- ❑ 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce heart disease
 - Protein Technologies International
 - Weston A. Price Foundation
-



Possible Implications

□ Confusion

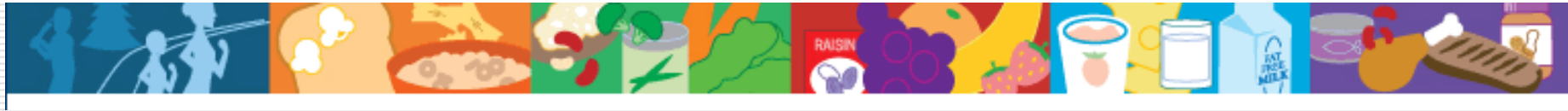
- What constitutes a healthy diet?
 - Who is actually benefiting?
 - People may be led to believe that they do not have to make any other lifestyle changes
 - Too much of a good thing...
-



Possible Implications

- “Nobody wants anything less than extra strength...Extra strength is the absolute minimum...Figure out what will kill me, and then back it off a little bit.”





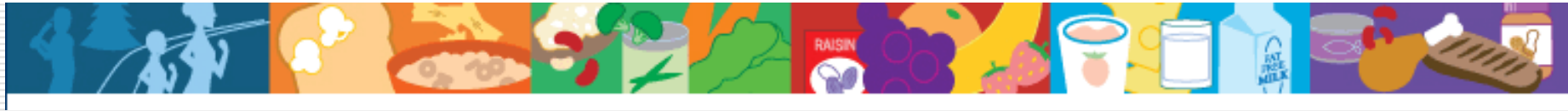
Bias in Nutrition Research

□ FDA

- It would be “speculative” to have advisory committees free of conflicts of interest

□ Center for Science in the Public Interest (CSPI)

- It would take only 1 week for advisors with conflicts of interest to be replaced
-



Recommendations

- Restore FDA's power to limit health claims
 - Make qualification statements clearer to avoid confusion
 - Make it clear that the positive effect proposed by a health claim is only the first step towards promoting health
 - Make it easier to eat healthy
-