

Scientific Review of Qualified Health Claims (QHC)

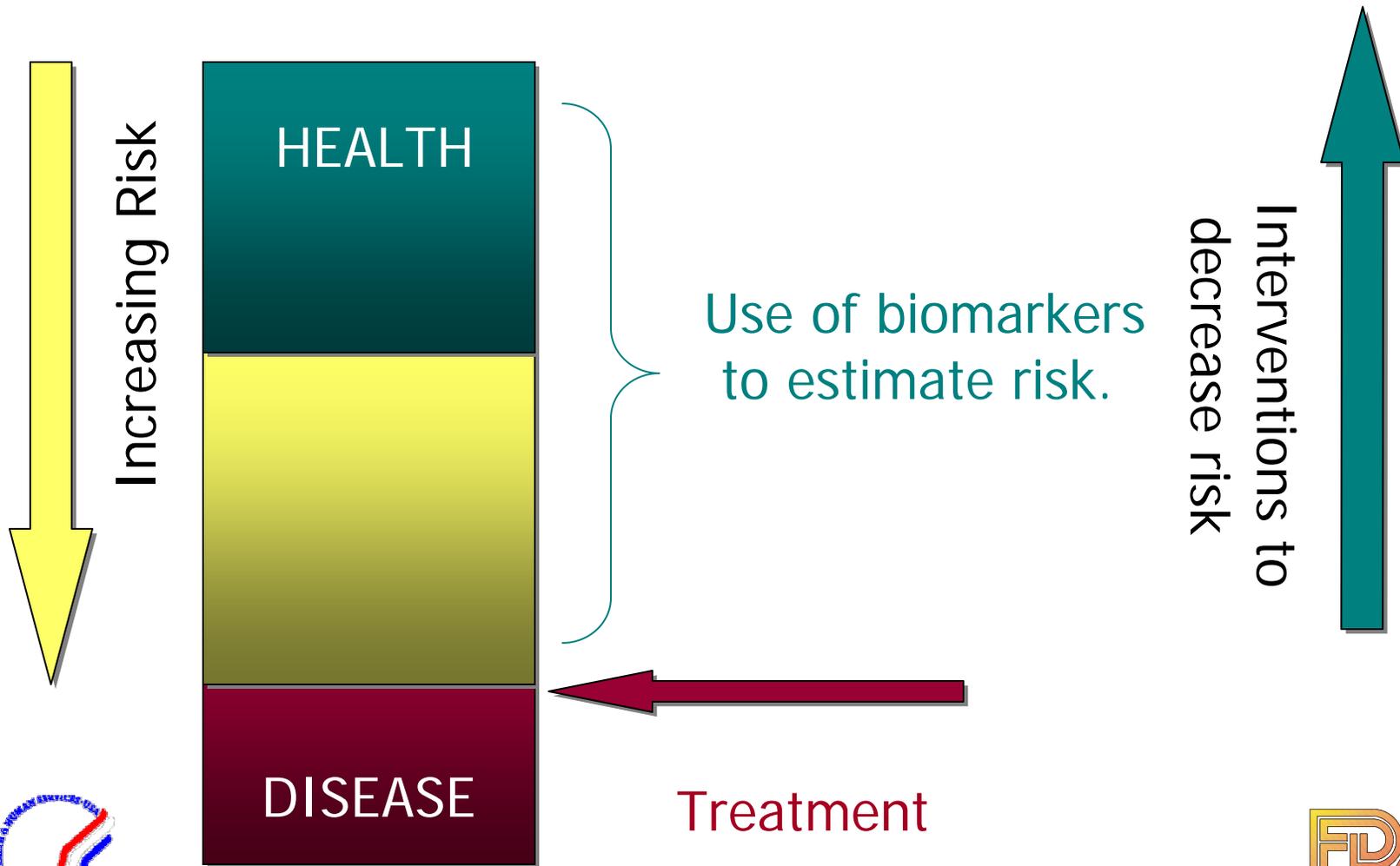
Barbara O. Schneeman, Ph.D.

Office of Nutritional Products, Labeling and Dietary Supplements

Center for Food Safety and Applied Nutrition
Food and Drug Administration



Reducing Risk for Disease



Background: Label Claims for Foods

- 1990 Nutrition Labeling and Education Act (NLEA) was enacted
 - Allowed for health claims based on significant scientific agreement (SSA) in food labeling.
- 1994 Dietary Supplement Health and Education Act (DSHEA) was enacted.
 - Provided for structure/function claims, claims of general well-being, and nutrient deficiency claims in dietary supplement labeling
- 1999: Pearson vs. Shalala (US Appeals Court)
 - 1st amendment protection of commercial speech
 - FDA must permit claims that do not meet SSA, if properly qualified to prevent consumers from being misled.
 - FDA issued letters of enforcement discretion for several claims as a result of the court decision



Development of framework for QHC

- October, 2000: FDA revoked the regulation codifying its decision to not authorize 4 claims that were the subject of the Pearson case.
- Court decisions:
 - Qualified Health Claims were subsequently allowed through enforcement discretion for antioxidant vitamins, 0.8 mg of folic acid, B-vitamins and vascular disease.
- QHCs reviewed before implementing the 2003 interim procedures
 - Omega-3 fatty acids and heart disease for dietary supplements
 - Selenium and cancer
 - Nuts and heart disease
 - Walnuts and heart disease
 - Phosphatidylserine and cognitive dysfunction and dementia



2002 Initiative FDA Task Force: *Consumer Health Information for Better Nutrition* (CHIBN)

- Report released July 10, 2003
- Established Interim Procedures:
 - Qualified Health Claims on Conventional Food & Dietary Supplements
 - Interim Evidence-Based Ranking System for Scientific Data
- Proposed a Consumer Studies Research Agenda
- 2005-6 CFSAN priority: Propose a regulatory strategy for qualified health claims
- Ongoing review of qualified health claim petitions under interim procedures.



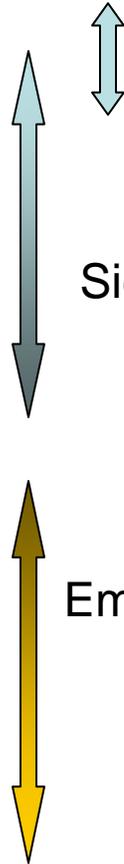
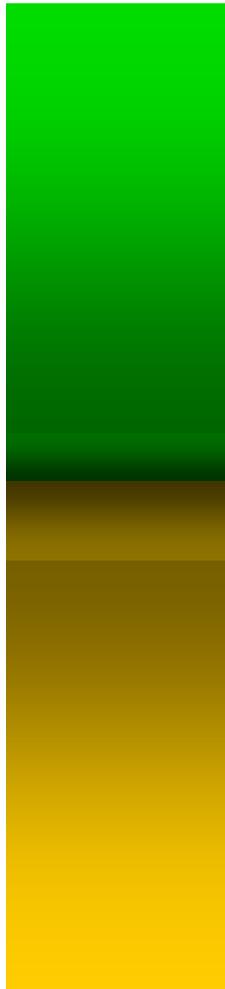
Health Claims for conventional foods and/or dietary supplements

- Health Claims authorized through rulemaking
 - Based on significant scientific agreement
- Qualified Health Claims
 - Claims that characterize the quality and strength of the scientific evidence if the claim is not based on significant scientific agreement.
 - Allowed through enforcement discretion under interim guidelines



Continuum of Scientific Evidence

Strength and consistency of scientific evidence



Scientific Consensus

Significant Scientific Agreement

Emerging Evidence

Some evidence and . . .
-not conclusive,
-limited and not conclusive,
-very limited and preliminary
evidence; little scientific evidence
to support, or
-benefit is highly unlikely/uncertain



Interim Procedures for Qualified Health Claims

- Qualifying Language to characterize level of scientific evidence.
 - B: ...although there is scientific evidence supporting the claim, the evidence is not conclusive
 - C: Some scientific evidence suggests...however, FDA has determined that this evidence is limited and not conclusive
 - D: Very limited and preliminary scientific research suggests... FDA concludes that there is little scientific evidence supporting this claim

...”the precise language...may vary depending upon the specific circumstances of each case”



Reviewing the Evidence 1999 and 2003

- Define substance/disease relationship
- Identify relevant studies
- Classify studies
- Rate studies for quality
- Rate for strength of body of evidence:
Quantity, quality, consistency, relevance
- Report “rank”



Status of qualified health claim petitions since release of CHIBN July, 2003-Oct, 2005

- Under the CHIBN initiative 17 petitions have been submitted to FDA for QHCs. Petitions often contain multiple claims for review.
- The total number of proposed QHCs reviewed by FDA is 75.
- FDA has issued letters of enforcement discretion for 16 claims.



Process for reviewing the scientific evidence

- Interim guidance from the *Consumer Health Information for Better Nutrition* task force report
- Letters of enforcement discretion lay out agency thinking and criteria for evaluation.
 - Available on the CFSAN web site: www.cfsan.fda.gov

