
Session 1

Barbara Schneeman, Ph.D.
ONPLDS-CFSAN-FDA



Approaches for substantiating health benefits of bioactive food components

- Establishing nutrient requirements
 - Dietary Reference Intakes
- PASSCLAIM framework
- Framework used by the Food and Drug Administration
- Population interest in specific health benefits
 - Are the claims accurate and reliable?
 - How is a causal relationship established?

What is the intended purpose?

- Treatment, mitigation, cure, or prevention
 - Drug Claim
- A food or food substance that lowers risk of disease in the general population
 - Health claim
- A dietary ingredient that maintains the healthy structure or function of the body
 - Structure-function claim



The question of 'drug' v. health claims?

- How can individuals lower risk v. treat or mitigate a disease state?
- When does evidence from treatment or mitigation of a disease state apply to reducing risk of disease?
- Consideration of genetic polymorphisms: What constitutes variation in the general population?



Questions addressed in Health Claims

- Have studies appropriately specified and measured the substance that is the subject of the claim?
- Have studies appropriately specified and defined the disease or health-related condition that is the subject of the claim?
- Are any and all conclusions about the substance/disease relationship based on the totality of publicly available scientific evidence?



Nature of Evidence Available

- Intervention Studies
 - Randomized, controlled trials
 - Clinical studies/trials
 - Controlled for confounders and bias
 - Appropriate study population
- Observational Studies
 - Vary in persuasiveness
 - Retrospective vs. prospective
 - Cohort and case-control studies
- Research synthesis (meta-analysis, reviews)
 - Useful for identifying relevant studies
- Animal and in vitro studies
 - Hypothesis-generating; explore mechanisms
 - Useful support but not sufficient by themselves



Continuum of Scientific Evidence

