

# **Reviews of Scientific Evidence to Substantiate Food and Supplement Claims in the U.S.**

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**Presented to the Reduced Risk Review Core Committee**

**Bethesda, MD, USA**

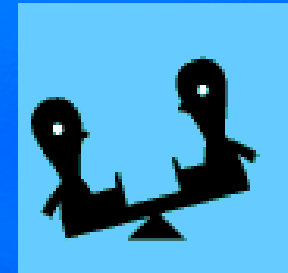
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## Why Food/Supplement Claims?

- We are not regulators
  - quasi, pseudo, or otherwise
- Neither fish nor flesh nor fowl
  - Tobacco is not a drug, food, or environmental hazard
- Our focus is the **scientific** basis for **conclusions** about reduced **risk**
- Offered as a selected point of reference

# Claims Inform Consumer

- **Claims are regulated**
- **Goals change**
- **Science changes**
- **Claims provide information**
- **How do we reflect changing science**
- **Role of scientists**





# U.S. Federal Regulatory Bodies for Foods, Drugs, and Supplements

- **Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN)**
  - Labels, safety
- **Federal Trade Commission**
  - Advertising

# Safety Issues

- **Foods presumed are safe**
- **Additives and contaminants are not**
- **Can you get too much of a good thing?**
  - **Total exposure**
  - **Toxicity**
  - **Food matrix and cooking**
  - **Unbalanced diet**

# FDA Regulatory Continuum

- **Drugs** ↔ **foods** ↔ **dietary supplements**
- **Different claims**
- **Sometimes the same material with different intentions**
- **Hard to draw bright lines between them**
- **Overlapping bureaucratic fiefdoms**



# Label Claims

- **Drug claims (not for foods)**
- **Dietary supplement claims (DSHEA)**
- **Structure or function claims (S/F)**
- **Health claims**
- **Nutrient content claims**

## Structure /Function Claims (S/F)

- **How it works in the body**
  - Milk helps builds strong bones
- **Derived from the nutrient content**
  - What is nutrient content
  - Narrowly defined
- **Can't be explicit or implied drug or health claim**
  - Milk cures osteoporosis
- **Weight of the evidence**



# Health Claims - NLEA

- Nutrition Label Education Act (NLEA)
- Expressly or by implication characterizes the relationship of any substance to a disease or health-related condition
- Excludes nutrient deficiency
- Must be otherwise healthy food
- Cannot cure, mitigate, or treat – drug claim
- Must prevent or reduce risk of disease

# Claims Approved Under NLEA

- Calcium and osteoporosis
- Dietary fat and cancer
- Dietary sat fat, cholesterol and CHD
- Fiber (grains, fruits & vegetables) and cancer
- **Sugar alcohol and dental caries**
- **Folate and neural tube defects**
- Fruits & vegetables and cancer
- Fruits, vegetables and fiber grain (sol fiber) and CHD
- Sodium and hypertension
- Soluble fiber from certain foods and CHD
- **Soy protein and CHD**
- **Stanols/sterols and CHD**

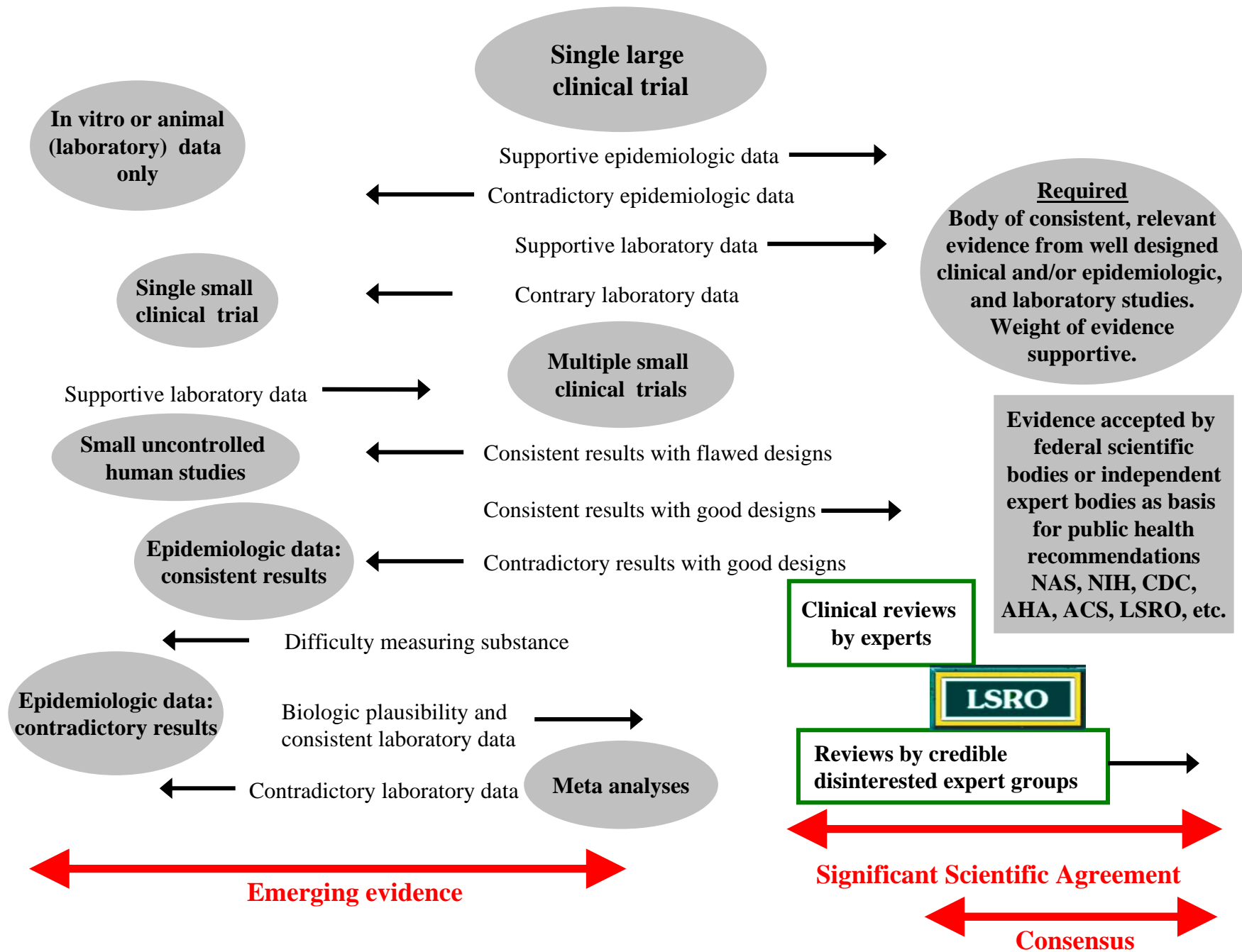
# Health Claims - FDAMA

- **FDA Modernization Act**
- **Based on published authoritative statements from government agency or NAS**
- **Only two since 1997**
  - **Whole grains, heart disease and cancer**
  - **Potassium, high blood pressure, and stroke**



# Level of Proof

- **Significant Scientific Agreement (SSA)**
  - Well designed studies
  - Generally recognized scientific procedures & principles
- **Reviewed by qualified experts**
- **Totality of the evidence**
- **Evaluate scientific relationship not wording**



# Impact of the Courts

- **Pearson v Shalala**
  - Free speech
  - Competent consumer
  - Weight of evidence?
- **Whitaker v Thompson**
  - Only potentially misleading
  - Credible evidence
- **Qualified health claims** for dietary supplements
- **Why not for foods?**



# Consumer Health Information for Better Nutrition (CHIBN)

- **McClellan proposed in Dec 2002**
- **Established committee in Jan 2003**
  - Crawford, Levitt, FDA, FTC, NIH
- **Goals**
- **Report issued July 10, 2003**

# CHIBN Goals

- **Give consumers truthful, understandable information for healthy choices**
- **Improve public health**
  - Improving consumer choice
  - Encourage competition based on health effects
- **Remove discrepancy between foods and dietary supplements**

# Qualified Health Claims

## How Qualified is Qualified?

- Although there is scientific evidence supporting...the evidence is not conclusive
- Some scientific evidence suggests...however, FDA has determined that this evidence is limited and not conclusive
- Very limited and preliminary scientific research suggests...FDA concludes that there is little scientific evidence supporting this claim.

### Health Claims Report Card



<b>A</b>	<b>High</b> Significant scientific agreement	<b>1</b>
<b>B</b>	<b>Moderate</b> Evidence is not conclusive	<b>2</b>
<b>C</b>	<b>Low</b> Evidence is limited and not conclusive	<b>3</b>
<b>D</b>	<b>Extremely Low</b> Little scientific evidence supporting this claim	<b>4</b>



# Qualified Health Claim Level of Proof

- Institute for Clinical Systems Improvement
- Adapted by American Dietetic Assoc.
- Modifications specific to FDA
- Human studies are necessary

# Qualified Health Claim Level of Proof (cont)

- **Identify relationship, collect literature**
- **Rate each study (Type, Quality)**
- **Rate Strength of Total Body**
  - **Quantity**
  - **Consistency**
  - **Relevance**
- **Rank strength of the evidence**

# FTC Substantiation Standard

- “competent and reliable scientific evidence”
  - Tests, analyses, research, studies, or other evidence
  - Based on the expertise of professionals in the relevant area
  - Conducted and evaluated objectively
  - By qualified
  - Using procedures generally accepted in the profession to yield accurate and reliable results



# Relationship of the Evidence to the Claim

- Do the studies measure
  - The product that is subject to the claim?
  - Specified the health effect subject to the claim?
  - Similar population to that will be consuming?
  - The extent, nature or permanence of effect that will be claimed?
  - Reflect the level of certainty of the claim?

# Types of Evidence

- Intervention studies (RCT)
- Observational studies
  - Case reports, case-series, case-control, cohort, cross-sectional, time-series, epidemiological
- Background support
  - Animal studies
  - In vitro studies
  - Testimonials, meta-analysis, reviews, etc

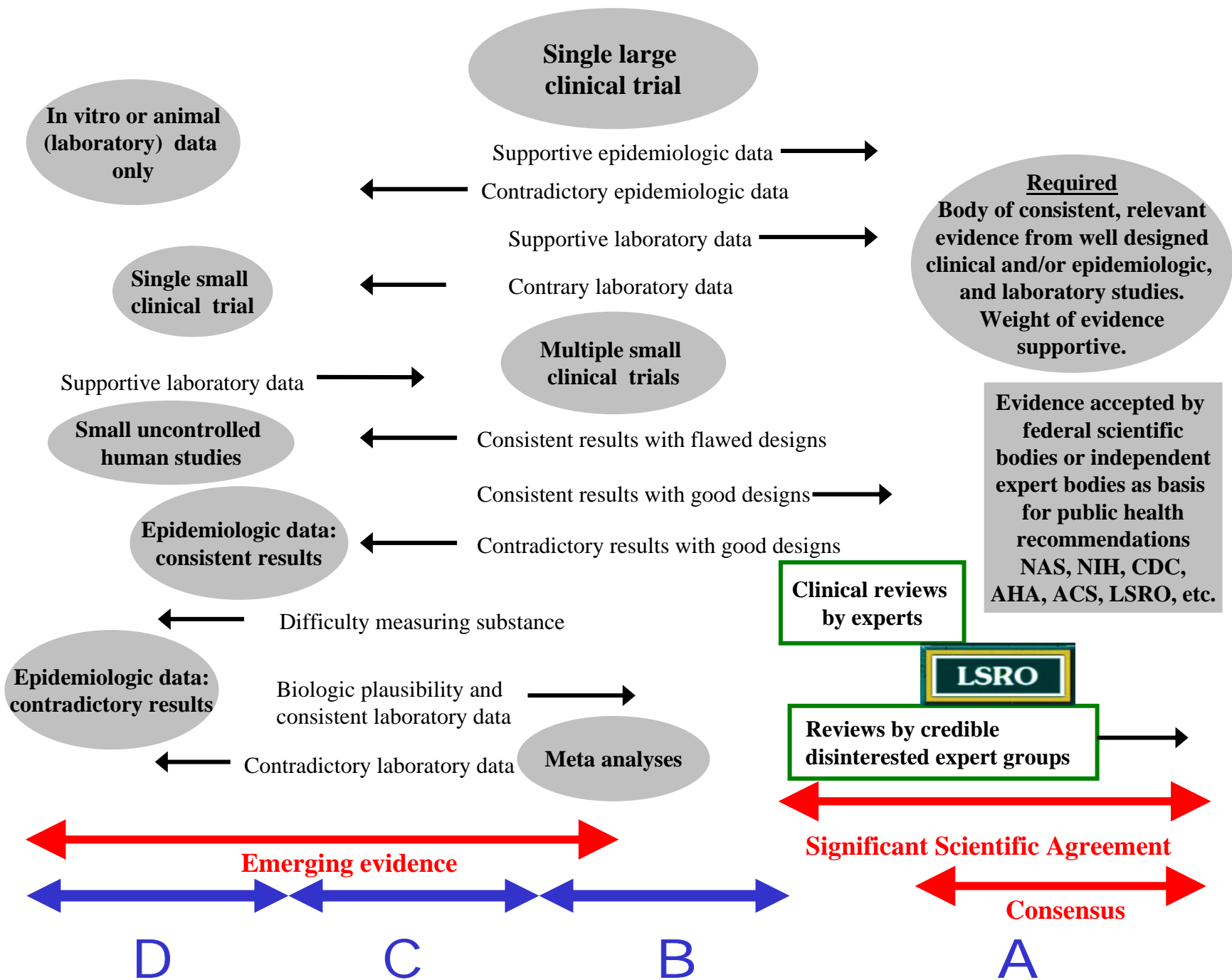
# Quality of Evidence

- Bias, confounders, and other limitations
- Adequacy and clarity of design
- Population (size, representative, inclusion/exclusion criteria, selection, randomized)
- Assessment of outcomes (methodology, quality control, well described, etc)
- Data analysis and assessment
- Peer review



# Totality of the Evidence

- No rule for how many or what combination of studies
- Quality and persuasiveness of each piece plus
- Consistency of the data a factor
- Consider the context of all available information



## Qualified Health Claim (11/2004)

- “Limited and not conclusive scientific evidence suggests that eating about 2 tb (23gm) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil.”



# Conclusions

- Though food claim substantiation is not directly relevant, it can be instructive
- Scientists should stick to the strengths, limitations, relevance of the scientific evidence
- Let others parse nuance and inference
- Leave the elegant wording to regulators and legislators

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