North Carolina Research at Kannapolis

David Murdoch of Dole Foods - $1 billion personal investment to study

Plants For Human Health

Partners

- Six North Carolina Universities
  - Including NC State, UNC, Duke
- Monsanto, Dole Foods, Murdoch Research Institute
- ARS ($1 million earmark in 2009

Science and Pseudoscience in Adult Nutrition Research and Practice

Reynolds Spector , Robert Wood Johnson Foundation

- In summary, the critics …. suggest that much nutritional research and practice is … science's laughingstock, for two reasons: much of the research, especially epidemiology/observational studies is pseudoscientific….and second, many practitioners and commercial interests do not readily acknowledge the truth.

The ARS program at Kannapolis Establish a "Proof of Concept" model for studying human health benefits of plant foods

- The opportunity:
  - Animal and cell culture studies suggest blueberries may help prevent age-related cognitive decline
- The problem:
  - This idea has not been tested in a well designed human trial
  - Past experience has shown us that not all people respond the same way to a food; this is because of variability in:
    - Human genetics
    - Human environment
    - Plant genetics
    - Plant environment

The ARS program at Kannapolis Establish a "Proof of Concept" model for studying human health benefits of plant foods

- Scientists in 3 disciplines:
  - Horticulture
    - Post Harvest processing
    - Varietal variation
  - BiochemistryCellular mechanisms
  - Human Nutrition
    - Well-designed clinical studies
    - Conducted in collaboration with a psychologist

The ARS program at Kannapolis Establish a "Proof of Concept" model for studying human health benefits of plant foods

- Cooperation across disciplines
- Characterization of variability in food and in the human
- Understanding of "responders" and "non-responders"
- Nutritional advice based on clinical studies

A call for "Evidence-Based Nutrition"

- Evidence based on well planned and executed clinical trials
- May require challenging prior assumptions and approaches

Evidence-based medicine (EBM)

(from Wikipedia)

- Applies the best available **evidence** gained from the scientific method to medical **decision making**.

- Assesses the quality of evidence of the risks and benefits of treatments (including lack of treatment).

- EBM seeks …..to apply these methods to ensure the best **prediction** of outcomes in medical treatment.

Scientific evidence for the function of a food ingredient:

1. Predicted (no evidence); Organic food is more nutritious ?


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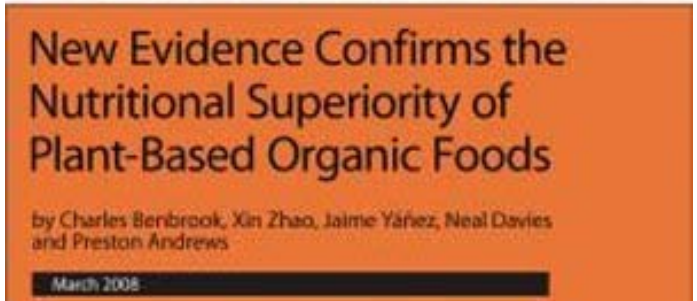
Why did weather men get it all so wrong about



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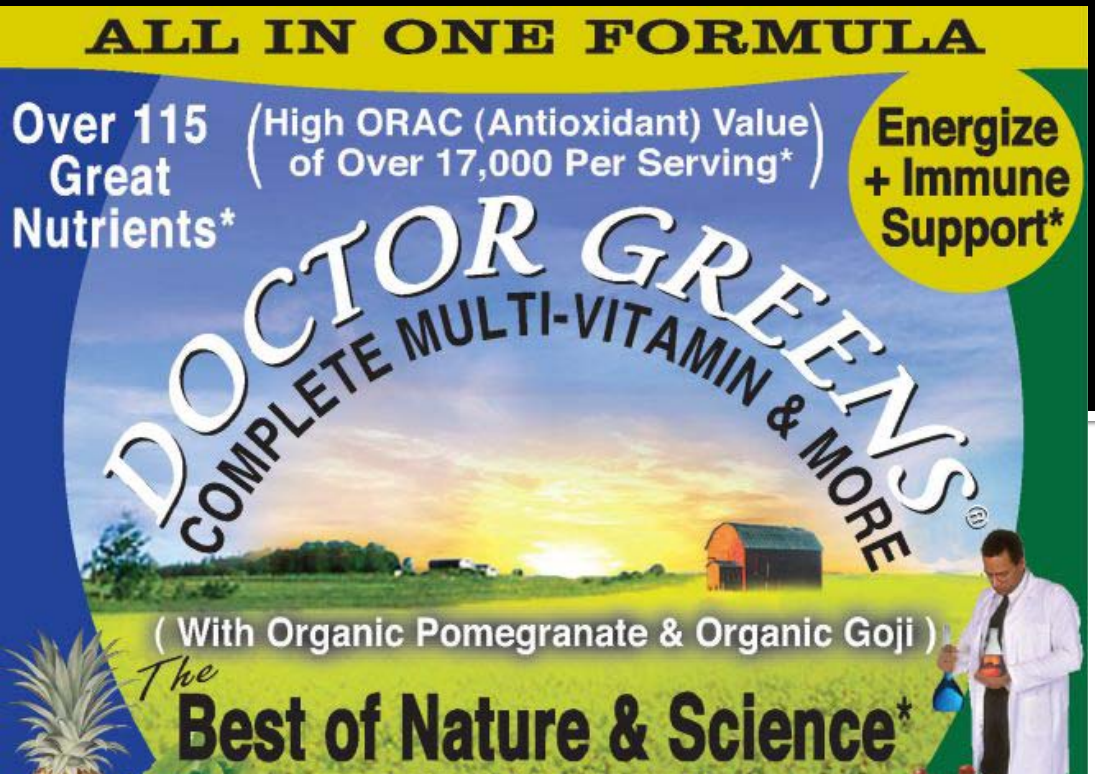

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But all the above only generate
HYPOTHESES

Evidence requires human studies

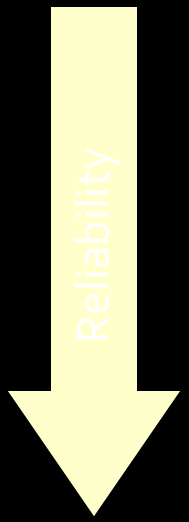
Scientific evidence for the function of a food ingredient:

1. Predicted (no evidence); Organic food is more nutritious ?
2. Inorganic chemistry; e.g. ORAC
3. In vitro; e.g. cell culture
4. Animal studies
5. Human – Epidemiology and ecological
6. Human – Clinical trials

Human Evidence

Clinical evidence for functionality: all is not equal

- Observational vs. Interventional evidence



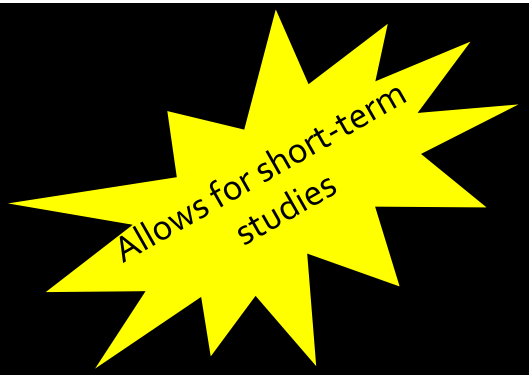
- Survey studies
- Longitudinal observational studies
- Case Control Studies
- Retrospective cohort studies
- **Prospective cohort studies**

Evidence of efficacy
Judging study value:

- Valid biomarkers

  NIH guidelines accepted by FDA

  Heart disease
  - *Serum cholesterol, triglycerides, LDL cholesterol*
  - *Blood pressure*
  - *Diagnosis of Cardiac event/stroke*
  - *Heart disease mortality (certified by pathologist)*



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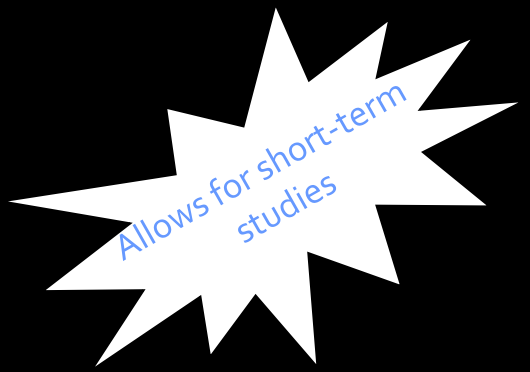
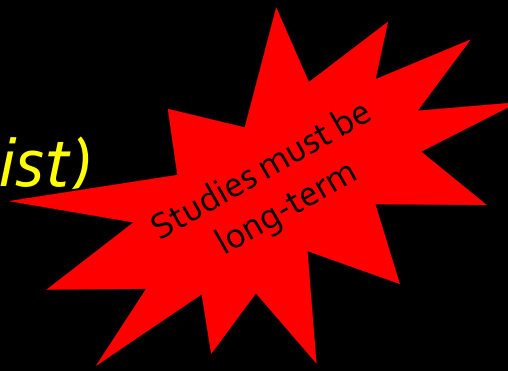
  Heart disease
  - *Serum cholesterol, triglycerides, LDL cholesterol*
  - *Blood pressure*
  - *Diagnosis of Cardiac event/stroke*
  - *Heart disease mortality (certified by pathologist)*

- Cancer
  - *Ademaetous Colonic Polyps*
  - *Diagnosis of cancer*
  - *Cancer mortality (certified by pathologist)*



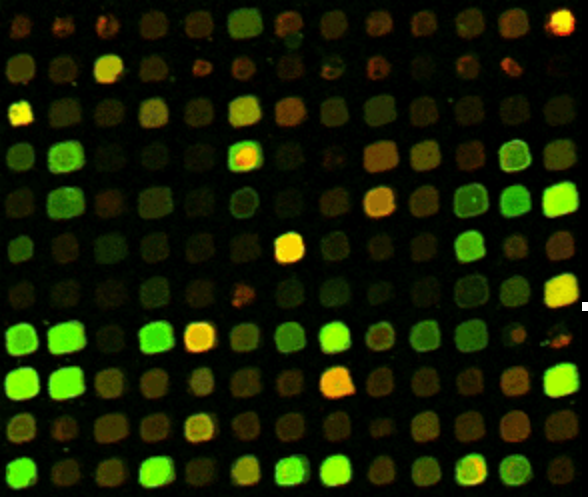


Evidence of efficacy
Judging study value:
How much is enough??

FCC:

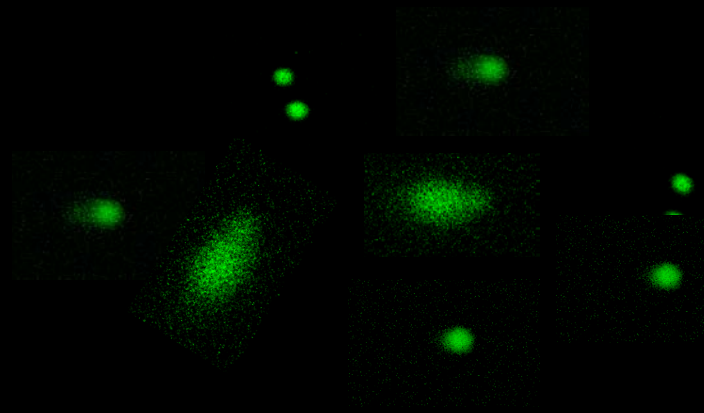
- Truthful and non-deceptive;
- Must have evidence to back up their claims
- Advertisements cannot be unfair.
- From point of view of the "reasonable consumer"
- "Express" and "implied" claims.

*Health or safety claims must be supported by **"competent and reliable scientific evidence"** - tests, studies, or other scientific evidence that has been evaluated by people qualified to review it.*



Evidence of efficacy
Judging study value:

- Valid biomarkers
  - Many common biomarkers NOT acceptable to FDA
    - *Cancer*
      - *PSA*
      - *COMET assay and similar*
      - *Gene activation*
      - *Enzyme activity*
      - *Circulating cytokines*



Evidence of efficacy
Judging study value:

- Valid biomarker
- Accurate estimate of intake
  - Validated Food Frequency Questionnaire
    - Secondary measures help validate:
      - Urinary nitrogen ~ protein intake
      - Doubly labeled water ~ energy intake
  - Surrogate markers of intake
    - Serum conc., enzyme activity, etc.

The American Journal of CLINICAL NUTRITION

Validation of a self-administered food-frequency questionnaire administered in the European Prospective Investigation into Cancer and Nutrition (EPIC) Study: comparison of energy, protein, and macronutrient intakes estimated with the doubly labeled water, urinary nitrogen, and repeated 24-h dietary recall methods

Anja Kroke, Kerstin Klipstein-Grobusch, Susanne Voss, Jutta Möseneder, Frank Thielecke, Rudolf Noack and Heiner Boeing ; AJCN1999, 70, 439-447

Evidence of efficacy
Judging study value:

- Relevant/Adequate survey population
- Valid baseline or comparative group
  - DRUGS cure ill health, *FOOD maintains good health*
  - Use Healthy subjects

Evidence of efficacy
Judging study value:

- Valid biomarker
- Accurate estimate of intake
- Relevant/Adequate survey population
- Valid baseline or comparative group
- Lack of 'bias'
- Adequate statistics
  - Sample size (Power analysis)
  - Randomization
  - Sequence effects (e.g. day length)
  - Proper design
    - Controls
    - Validated measures

Evidence of efficacy
Judging study value:

- Valid biomarker
- Accurate estimate of intake
- Relevant/Adequate survey population
- Valid baseline or comparative group
- Lack of 'bias'
- Adequate statistics
- Are conclusions justified?
  - Do data support conclusions?
  - Where are conclusions published?
  - Are they relevant to the target population?
  - Do they fit known chemistry/metabolism?

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Judging study value:

- Valid biomarker
- Accurate estimate of intake
- Relevant/Adequate survey population
- Valid baseline or comparative group
- Lack of 'bias'
- Adequate statistics
- Are conclusions justified?
- Studies in context of:
  - Whole Food (not isolated component)
  - Overall diet
  - Lifestyle

Summary

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- Kannapolis is "Proof of Concept"

Summary

- We need to “Get it right” or the public will lose faith