1:15 – 1:45 **Presentation 2: Safety: The Concept, Its Measurement, and Reporting**

Objectives: (1) Explain the concept of safety and how it is defined, measured, studied, and reported in regard to dietary supplements, (2) provide examples to illustrate the ways in which the safety of various supplement ingredients have been evaluated, and (3) discuss the patchwork of systems in place to monitor for adverse effects of supplements and how safety concerns vary by population subgroups.

Elizabeth A. Yetley, Ph.D.
NIH Office of Dietary Supplements (retired)

1:45 – 2:00 **Questions for Speaker**

2:00 – 2:30 **Presentation 3: Identity and Quality**

Objectives: (1) Illustrate that the mix of bioactives in many supplements presents formidable analytical challenges in assaying the identity, characteristics, and quality of ingredients,
(2) discuss methods by which constituents are (or could or should be) assayed in supplements to ensure quality, including specifications for identity, purity, and strength,
(3) note activities to develop standards and reference materials for ingredients and why they are important, (4) note strengths and weaknesses of commercial efforts to assess product quality, and (5) describe the Product Quality Working Group at NIH's National Center for Complementary and Alternative Medicine (NCCAM).

Joseph M. Betz, Ph.D.
NIH Office of Dietary Supplements

2:30 – 2:45 **Questions for Speaker**
2:45 – 3:00 **Questions and Discussion With Session 4 Speakers**
3:15 – 5:15 **(Optional) Special Event**

Tour of the NIH Clinical Center, National Library of Medicine, and overall NIH Campus.

DAY 3: Wednesday, June 3, 2009: Meeting the Stakeholders

8:30 – 1:00 Attendees will visit with those who study, advocate, regulate, or educate on dietary supplements in Washington DC. Questions for speakers to address:
(1) Describe the purposes of your organization (agency, etc.) in relation to dietary supplements. What are its perspectives and views regarding these products?, and
(2) describe your activities in matters related to supplements (including manufacture, marketing, and regulation) and in providing information/education about these products.

8:30 – 9:30 **Panel 1: Legislative Opportunities**

Location: Russell Senate Office Building, Washington DC (Bounded by Constitution Avenue, First Street, Delaware Avenue, and C Street NE)
Senator Orrin G. Hatch (R-Utah)
United States Senate

Donna V. Porter, Ph.D., R.D.
Congressional Research Service

10:45 – 11:45 **Panel 2: Face to Face With the Industry**
Location: Wilbur J. Cohen Building, Washington DC (330 Independence Avenue, SW)

Steven M. Mister, Esq.
Council for Responsible Nutrition

Daniel Fabricant, Ph.D.
Natural Products Association

Steven Dentali, Ph.D.
American Herbal Products Association

11:45 – 12:45 **Panel 3: Meet the Consumer Groups and Media**
Location: Wilbur J. Cohen Building, Washington DC

David Schardt, M.S.
Center for Science in the Public Interest

Peter Lurie, M.D., M.P.H.
Public Citizen's Health Research Group

Rob Stein
The Washington Post

12:45 – 1:00 **Questions and Discussion With Speakers**
1:00 – 2:30 **(Optional) Lunch at National Museum of the American Indian**

DAY 4: Thursday, June 4, 2009: Assessing the Health Effects of Supplement Ingredients and Locating Information

8:30 – 12:00 ***Session 5: Doing the Studies***

Goals: (1) Provide an overview of the different types of research on dietary supplements, the kinds of information each type provides, and their relative strengths and weaknesses,
(2) give examples of how these studies have advanced understanding of specific supplements, (3) describe considerations to be addressed in the conduct of a research study on supplements, and (4) present good and bad examples of how dietary supplements have been characterized in published journal articles.

Each presentation is 30 minutes followed by 15 minutes of questions and discussion.

8:30 – 9:00 **Presentation 1: The Different Types and What They Tell Us**

Objectives: (1) Provide an overview of the range of research studies on supplement, addressing their respective strengths and weaknesses and what each contributes to the mix of knowledge, and (2) describe the different levels of evidence from anecdotal reports to clinical trials and evidence-based reviews.

Paul D. Sorlie, Ph.D.
NIH National Heart, Lung, and Blood Institute

9:00 – 9:15 **Questions for Speaker**

9:15 – 9:45 **Presentation 2: Case Study: Garlic**

Objectives: (1) Use this particular dietary supplement as an example to illustrate the range of studies described in the previous talk and how each type of study has contributed to overall knowledge of this ingredient, and (2) describe some issues in conducting research on garlic products and assessments of their value and safety.

John Milner, Ph.D.
NIH National Cancer Institute

9:45 – 10:00 **Questions for Speaker**
10:00 – 10:15 **Break**

10:15 – 11:00 **Presentation 3: Research-Design Issues With Epidemiological Studies on Dietary Supplements**

Objectives: (1) define nutritional epidemiology as it pertains to dietary supplements,
(2) describe the types and sources of measurement error, methods used to adjust for it, and how it may influence research findings and study interpretations, and (3) identify other variables that can

affect the results of epidemiological studies on supplements and how they need to be recognized and/or addressed prior to conducting the study.

Christopher T. Sempos, Ph.D.
NIH Office of Dietary Supplements

10:45 – 11:00 **Questions for Speaker**

11:00 – 11:30 **Presentation 4: Conducting a Clinical Trial With Dietary Supplements**

Objectives: (1) Describe the institutional, research, regulatory, and other considerations to be addressed in conducting a study on supplements, (2) discuss the many variables that can affect the results of clinical trials on supplements and how they need to be recognized and/or addressed prior to conducting the study, and (3) address the need to fully characterize the supplement under study, using examples from published studies.

Robert M. Russell, M.D.
NIH Office of Dietary Supplements

11:30 – 11:45 **Questions for Speaker**
11:45 – 12:00 **Questions and Discussion With Session 5 Speakers**
12:00 – 1:30 **Lunch**

1:30 – 5:00 ***Session 6: Finding Information on Dietary Supplements***

Goals: (1) Participants will learn the purpose and value of several databases that inform users about research on dietary supplement ingredients, identify the contribution of dietary supplements to total nutrient intakes from all sources, and provide data on the nutrients and bioactive components in specific foods. They will become familiar with the content and navigation of these databases and complete several exercises to learn the value and limitations of these resources.

Each presentation is 30 minutes followed by 15 minutes of questions and discussion.

1:30 – 2:00 **Presentation 1: MEDLINE/PubMed Database**

Susan M. Pilch, Ph.D., M.L.S.
NIH Library

2:00 – 2:15 **Questions for Speaker**

2:15 – 2:45 **Presentation 2: IBIDS (International Bibliographic Information on Dietary Supplements) Database**

Rebecca B. Costello, Ph.D.
NIH Office of Dietary Supplements

2:45 – 3:00 **Questions for Speaker**

3:00 – 3:15 **Break**

3:15 – 3:45 **Presentation 3: RCDC (Research, Condition, and Disease Categorization), RePORT (Research Portfolio Online Reporting Tool), HNRIM (Human Nutrition Research and Information Management System), and CARDS (Computer Access to Research on Dietary Supplements)**

Karen S. Regan, M.S., R.D.
NIH Office of Dietary Supplements

3:45 – 4:00 **Questions for Speaker**

4:00 – 4:30 **Presentation 4: Characterizing Supplements in Journal Articles**

Objectives: (1) Provide examples from the published literature to demonstrate both superior and inadequate descriptions of supplement identity, purity, and strength, (2) explain why adequate characterization of dietary supplements in published research is important to forwarding the research agenda on specific supplements, and (3) discuss recommendations from various professional groups to researchers for characterizing the supplements being evaluated in various trials and the details that should be provided when preparing manuscripts.

Christine A. Swanson, Ph.D., M.P.H., R.D.
NIH Office of Dietary Supplements

4:30 – 4:45 **Questions for Speaker**

4:45 – 5:00 **Questions and Discussion With Session 6 Speakers**

5:30 – ??? **(Optional) Drinks & Dinner in Bethesda**
(We'll start at BlackFinn, 4901 Fairmont Avenue; near "Bethesda" stop on Metro's red line)

DAY 5: Friday, June 5, 2009: The Big Picture

8:30 – 12:30 ***Session 7: Science, Action, Advice, and Policy***

Goals: (1) Describe how public and regulatory policies pertaining to dietary supplements is generally built over time upon a strong foundation of science, (2) illustrate these points with case studies on vitamin D and the Dietary Reference Intakes (DRIs), (3) discuss the issues and challenges of communicating information about supplements to various audiences, and (4) provide a final opportunity to ask questions and discuss supplement-related issues with ODS staff and guests.

Each presentation is 30 minutes followed by 15 minutes of questions.

8:30 – 9:00 **Presentation 1: NHANES and Biomarkers of Exposure**

Objectives: (1) Define biomarkers and how they are selected and used to evaluate exposure and status to various ingredients found in supplements, (2) discuss how biomarkers are identified, evaluated, measured, and used for specific nutrients, (3) describe the strengths and weaknesses of using biomarkers as surrogate measures of exposure and how some biomarkers are more strongly associated with exposure than others, and (4) provide overview of the National Health and Nutrition Examination Survey (NHANES).

Clifford L. Johnson, M.S.P.H.
National Center for Health Statistics

9:00 – 9:15 **Questions for Speaker**

9:15 – 9:45 **Presentation 2: Case Study: Vitamin D**

Objectives: (1) Provide overview of vitamin D, including its effects on health, metabolic trafficking, and fate, (2) describe the factors, forces, and people involved in translating science to public policy for vitamin D, (3) describe the reasons and sources of debate among vitamin D experts as to "optimal" levels of intake and their benefits, and (4) describe the "Vitamin D Initiative" at the NIH and note the re-evaluation of recommended intakes for vitamin D and calcium by the Food and Nutrition Board.

Patsy M. Brannon, Ph.D., R.D.
Cornell University

9:45 – 10:00 **Questions for Speaker**
10:00 – 10:15 **Break**

10:15 – 10:45 **Presentation 3: Case Study: Probiotics**

Objectives: (1) Provide overview of probiotics and their availability in both foods and dietary supplements, (2) describe some unique issues in conducting research on these products and why the literature to date provides little consensus on their value and safety.

Marguerite Klein, M.S.
NIH Office of Dietary Supplements

10:45 – 11:00 **Questions for Speaker**

11:00 – 11:30 **Presentation 4: Informing Policy Through Science**

Objectives: (1) Discuss how science is used to advance knowledge about nutrition and dietary supplements and to develop public policies about these products, and (2) illustrate the science-policy continuum using the Dietary Reference Intakes as an example.

Linda D. Meyers, Ph.D.
Food and Nutrition Board, Institute of Medicine of the National Academies

11:30 – 11:45 **Questions for Speaker**
11:45 – 12:00 **Questions and Discussion With Session 7 Speakers**

12:00 – 12:30 **Final Questions and Discussion With ODS Staff and Speakers**

12:30 **Adjourn**

参考資料2：ダイエタリーサプリメント　リサーチプラクティカム2009にて使用されたＦＤＡ担当官のレクチャースライド

FDA Regulation of Dietary Supplements

Vasilios H. Frankos, Ph.D.
Director, Division of Dietary Supplement Programs
Food and Drug Administration

Laws Regulating Dietary Supplements

- Dietary Supplement Health and Education Act of 1994 (DSHEA) amended the Federal Food, Drug, and Cosmetic Act (FFDCA)
  - Defined the term dietary supplement
  - Included dietary supplements under the FFDCA adulteration provisions
  - Established requirements for new dietary ingredients

What is a Dietary Supplement?

"...a product (other than tobacco) intended to supplement the diet that bears or contains one or more" dietary ingredients

What is a Dietary Supplement?

- Vitamin, mineral, amino acid
- Herb or other botanical
- Dietary substance for use by man to supplement the diet by increasing the total dietary intake
- Concentrate, metabolite, constituent, extract, or combination of any ingredient above

Other Requirements for Dietary Supplements

Intended for ingestion

Pill, capsule, liquid, powder, "other"

- Cannot be represented as a:
  - Conventional food
  - Sole item of a meal
  - Total diet
- Must be labeled as a dietary supplement

Excluded As Dietary Supplements (DSs)

- Articles approved, or authorized for investigation, as a new drug, antibiotic, or biologic that were not first marketed as a dietary supplement or as a food

1

New Dietary Ingredients (NDIs)

- Those that were not marketed in the U.S. prior to October 15, 1994
- No authoritative list of dietary ingredients that were marketed before October 15, 1994
- The manufacturer of a dietary supplement is responsible for ensuring that it is safe before it is marketed in the U.S.
- FDA is responsible for taking action against any unsafe dietary supplements after they are marketed in the U.S.

NDI Premarket Notifications

- Manufacturers or distributors must submit a notification to FDA 75 days before a new dietary ingredient is marketed or introduced for marketing in the U.S.
- This notification must meet the requirements of 21 CFR § 190.6.

NDI Premarket Notifications

- Amount of the NDI in the dietary supplement
- Conditions of use recommended or suggested in the labeling of the dietary supplement
- History of use or other evidence of safety establishing that the NDI, when used under the conditions recommended or suggested in the labeling, is reasonably expected to be safe.

NDI Notification Process

- For 90 days after the "filing" date, FDA will not disclose the existence of, or information contained in, the NDI notification.
- Afterwards, the NDI notification will be placed on public display at FDA's Documents Management Branch in Docket number FDA-1995-S-0039.

Structure Function Claim Notification

- Mandatory notification of the FDA within 30 days of marketing (21 CFR 101.93)
- 30 day notification contains:
  - Name of the DS including the brand name
  - Name of the company marketing the product and a signature of the submitter
  - Text of the structure function claim (does not need to have the support for the statement included)
  - Name of the dietary ingredient/s in the DS that is subject of the claim

Response of FDA to a 30 Day Structure Function Claim Notification

- No timetable for FDA review
- If no concern, the notification will be filed with the FDA dockets office (docket # FDA-1997-S-0039) without any comment.
- If FDA has concern, the notifier will be informed in writing, and the notification will be filled with comment in the FDA dockets office (docket # FDA-1997-S-0039).

Final Guidance – Structure Function Substantiation

- January 5, 2009 Federal Register: 74 FR 304
-
- Describe the nature of the claim and the amount, type, and quality of evidence
- Why is guidance helpful?
  - Label and advertising claims must be truthful and not misleading
  - Modeled on FTC standard

What is the substantiation standard?

- "Competent and reliable scientific evidence"

  "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results"

Adulteration of DSs

- A DS is adulterated if it:
  - Poses a significant or unreasonable risk of illness or injury when it is used as directed on the label
  - Poses an imminent hazard to public health or safety
  - Contains a poisonous or harmful substance
  - Contains an NDI unless:
    - There is history of use as a food in the U.S. in a form not chemically altered, or
    - There is evidence of safety and the NDI has been reviewed by FDA through the 75-day premarket notification process

Compliance Activities

- Four Areas of Concern
  - Contaminants, including drug ingredients
  - New Dietary Ingredients
  - Conventional food - dietary supplement boundary
  - Illegal disease claims

Chemical Contaminants

- Broad range
  - Heavy metals
    - Environmental origin (i.e., lead)
    - Accumulated (i.e., arsenic)
  - Non-metal environmental contaminants
    - Aflatoxins, etc.
    - Dioxins, etc.
  - Intentional contaminants
    - Steroids
    - Melamine
    - Drugs (Viagra)

Chemical Contaminants

- From processing
  - Hydrocarbons, from drying with engine exhaust
- From contaminating plants
  - Microcystin in blue-green algae
  - Substitutions (Aristolochia)
  - Other plants inadvertently collected

Filth in Dietary Supplements

- Soil, insects, decomposition products, etc.
  - Which are of concern?
  - Do they vary for different plants?
  - Cultivation/harvest effects?
- Safety or economic concern?
- Mitigation or correction?

Dietary Supplement Pesticide Residues

- Scope of contamination
- Environmental vs. cultivation practice
- Mitigation/corrections
- Analytical methods

Microbiological Contamination

- Nature and scope of the problem
- Safety or quality?
- Methods for mitigation (Irradiation)?
- Analytical methods
  - Direct methods
  - Markers?

Current Dietary Supplement Good Manufacturing Practices (CGMP)

- June 25, 2007 - FDA published the DS CGMP rule.
- Require proper controls are in place so dietary supplements are processed in a consistent manner and produce a high quality product that is not adulterated with contaminants or impurities, and are accurately labeled.
- The DS CGMPs should help prevent inclusion of the wrong ingredients, too much or too little of a dietary ingredient, contamination (e.g. natural toxins, bacteria, pesticides, glass, and heavy metals such as lead), and improper packaging and labeling.

Enforcement Discretion

- The requirements of this final rule will not apply to certain health care practitioners based on enforcement discretion (acupuncturists, naturopaths, herbalist, etc.)
- Two potential safeguards : (1) adequate training in the professional practice and (2) an individual client and practitioner relationship.
- Enforcement discretion will not apply to practitioners who prepare batches of herbs and sell them to individual consumers without determining whether the dietary supplement is appropriate for each consumer's needs in a one-on-one personal consultation i.e. provide them for mass sale through the internet or retail outlets.

Major Requirements

- Effective August 27, 2007 the final rule codifies (CFR 21 part 111) the specific current good manufacturing practices (CGMPs) that must be used to manufacture dietary supplements.
- Final DS CGMP rule does not apply to raw ingredient manufacturers, although they will continue to need to meet the food CGMP regulations.
- The CGMPs apply to all domestic and foreign companies that manufacture, package, label or hold dietary supplements, including those involved with the activities of testing, quality control, packaging and labeling, and distributing them in the U.S.

Major Requirements

- Staggered three-year compliance inspection phase-in for small businesses. FDA inspections begin in June 2008 for large companies, June 2009 for companies with 20- 500 employees, and June 2010 for companies with fewer than 20 employees.
- The final rule is organized into 16 subparts that focus on specific aspects of the manufacturing process or addressing specific issues

Major Requirements

The requirements include provisions related to:

- the design and construction of physical plants that facilitate maintenance, cleaning,
- proper manufacturing operations,
- quality control procedures,
- testing final product or incoming and in process materials,
- 100% testing for identity of incoming dietary ingredients
- handling consumer complaints, and
- maintaining records.

CGMP's - Enforcement

- When a violation of the law or a regulation arises, FDA can take a number of actions to protect the public.
- For dietary supplements, as with other products, the agency may initially work with the product's marketer to correct the problem voluntarily.
- If that fails, the agency may bring a lawsuit to seize any product and/or enjoin the firm marketing it.
- When warranted, FDA also seeks criminal penalties – including prison sentences – against parties who break the law.
- FDA would evaluate what action would be appropriate on a case-by-case basis depending on the particular facts and circumstances.

Dietary Supplement and Nonprescription Drug Consumer Protection Act

- Starting December 22, 2007 any serious adverse events reported to a manufacturer must be reported to FDA through MedWatch 15 business days after the report is received.
- Any new medical information must be reported to FDA within 1 year of the initial report and firms are required to maintain records of AERs for six years.
- Serious AERs are defined as death, a life threatening experience, in patient hospitalization, persistent or significant disability or incapacity, congenital abnormality or birth defect, or requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under one of the above examples.

What Guidance Does FDA Provide?

- Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act
  http://www.cfsan.fda.gov/~dms/dsaergui.html
- Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act
  http://www.cfsan.fda.gov/~dms/dsaergu2.html

Number of voluntary and mandatory Dietary Supplement AER Reports for 2008

	Mandatory Adverse Event Cases	Voluntary Adverse Event Cases	Adverse Event Total Cases
2006	0	317	317
2007	0	350	350
2008	672(62%)	418 (38%)	1080 (10 duplicates)

Number of CAERS cases consuming dietary supplements and experiencing an adverse events, by gender from January 1, 2008 through December 31, 2008

Number of Cases (%)

Gender	From Voluntary Reports	From Mandatory Reports
Total Number of Cases	418	672
Female	218 (52.1%)	163 (38.5%)
Male	161 (38.7%)	196 (29.2%)
Unknown	9 (2.2%)	13 (2.0%)

Number of CAERS cases by dietary supplement product classification 2008

Number of Cases (%)

Dietary Supplement Product Classification	From Voluntary Reports	From Mandatory Reports
Total Number of Cases	418	672
Vitamin	47 (11.2%)	257 (38.1%)
Mineral	15 (3.7%)	126 (18.9%)
Protein	5 (1.2%)	11 (1.6%)
Herbal and Botanical	5 (1.2%)	11 (1.7%)
Herbals and Botanicals (other than Ginseng)	13 (3.1%)	28 (4.2%)
Animal Derivatives and Extracts	1 (0.2%)	0 (0%)
Fatty acid Lipids	11 (2.6%)	63 (9.4%)
Fiber	1 (0.2%)	22 (3.3%)
Multiple Natural Product Combination	35 (8.4%)	154 (22.9%)

Economically Motivated Adulteration (EMA)

- FDA will have a public meeting pertaining to economically motivated adulteration (EMA) on May 1, 2009.
- The purpose of the meeting is to stimulate and focus a discussion about ways in which industries and regulatory agencies can better predict and prevent economically motivated adulteration.
- FDA requests interested parties to submit oral and written comments at the meeting or to the public docket.

Economically Motivated Adulteration (EMA)

- Melamine: In March of 2007, FDA first received reports of kidney failure among cats and dogs and identified melamine contamination of certain brands of pet food as the causative agent. FDA received approximately 18,000 reports of sick pets.
- Oversulfated chondroitin sulfate (OSCS) in Heparin : January 2008, FDA received reports of U.S. cases of adverse reactions in pediatric dialysis patients. Investigations indicated that the adverse events appeared to be associated with heparin contaminated with oversulfated chondroitin sulfate (OSCS).

Economically Motivated Adulteration (EMA)

- Adulteration of glycerin, by diethylene glycol (DEG) has resulted in several mass poisonings around the world in the past two decades.
- Melamine in infant formula: In September 2008, FDA issued a Health Information Advisory in response to reports of melamine contaminated milk-based infant formula manufactured in China. Melamine was apparently added to diluted milk in order to increase measured nitrogen levels (indicators of protein content) and thereby enhance its perceived quality.

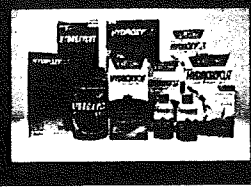
FDA Warns Consumers to Stop Using Hydroxycut Products

May 1, 2009, FDA received 23 reports of serious health problems ranging from jaundice and elevated liver enzymes, an indicator of potential liver injury, to liver damage requiring liver transplant.

Other health problems reported include seizures, cardiovascular disorders, and rhabdomyolysis

Hydroxycut Recall

- Although the FDA has not received reports of serious liver-related adverse reactions for all Hydroxycut products, Iovate agreed to recall all 14 Hydroxycut products



Total Body Formula Warning

- March 27, 2008, the FDA issued a press release warning consumers not to purchase or consume the following products: Total Body Formula in the flavors of tropical orange and peach nectar, and Total Body Mega Formula in the orange/tangerine flavor.
- This warning was in response to the growing number of reports of illness associated with the consumption of these products.

Total Body Nutrition Metal Analysis

- Total Body Nutrition product samples revealed "extremely high levels of selenium--up to 40,800 micrograms per recommended serving, or more than 200 times the 200 microgram labeled amount of selenium per serving."
- Samples also contained up to 3,426 micrograms of chromium per recommended serving, which is 17 times the recommended intake (35 to 45 micrograms per day).

参考資料３：ダイエタリーサプリメント　リサーチプラクティカム 2009 にて使用されたＦＴＣ（Federal Trade Commission）担当官のレクチャースライド

FEDERAL TRADE COMMISSION

Dietary Supplements: What the FTC Does

Dietary Supplement Research Practicum
NIH Washington, D.C.

June 1, 2009

Michelle Rusk
Division of Advertising Practices

Overview

- FTC Jurisdiction/ Coordination with FDA
- FTC advertising law basics
- FTC enforcement actions

FTC Mission

"Out of warranty? You are still eligible to reactivate warranty coverage. This is the final call before we close the file."

FTC Mission

- Small, independent law enforcement agency
- Broad mandate: stop deceptive and unfair practices in commerce
- Policing health fraud remains a big part of our mission

FTC/FDA Coordination

- Overlapping authority
- Liaison agreement
  - FDA - Labeling
  - FTC - Advertising
- Two agencies coordinate closely on food and dietary supplement policy issues

FTC/FDA Interaction

- FTC legal framework/approach differs from FDA:
  - Primarily a law enforcement agency
  - No pre-market approval process
  - No regulatory distinction between product categories
  - No regulatory distinction between health, disease, and structure/function claims

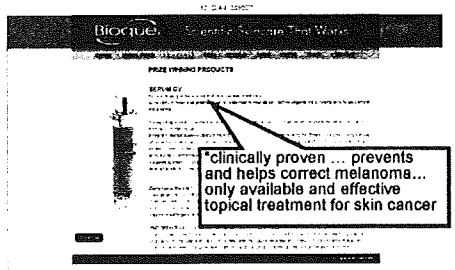
FTC/FDA Interaction

- Complementary, consistent actions
- Avoid duplication
- Joint actions use unique tools of each agency
- Rely on nutrition and science expertise of FDA
- Defer to FDA on content, purity, and safety

Joint Internet Health Fraud Sweeps

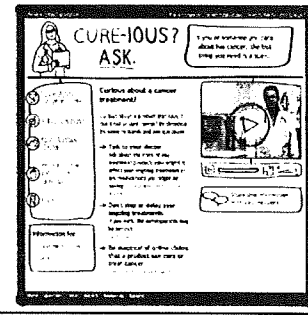
- **2007 Internet surf for cancer cures**
- **FTC/FDA/Canada joint project**
- **11 FTC enforcement actions**
- **Laetrile, shark cartilage, essiac tea, medicinal mushrooms, black salve…**
- **Ineffective and often dangerous**
- **Consumer outreach effort**

Joint Internet Health Fraud Sweeps



Bioque Technologies, Inc. *(Proposed Consent 2008)*

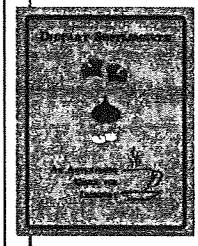
Internet Health Fraud Sweeps



FTC'S Role

- **FTC Act, Sections 5 & 12**
- **Advertising must be truthful and not misleading**
- **Objective claims must be substantiated before they are made**

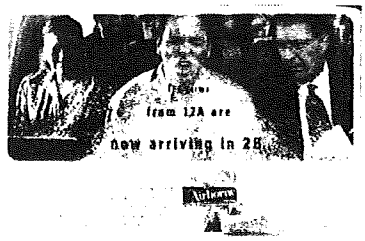
FTC Advertising Case



1. What claims are conveyed?

- **Consumer driven**
- **Express & implied claims**
- **Net impression**
- **Testimonials convey efficacy**
- **Disclosure of material information***

Ad Meaning



Ad Meaning

- Vitamins A, C, E, zinc, selenium …
- "clinically proven" to prevent/reduce risk of cold, other sickness; help fight germs
- $30 million in refund program, including private class action settlement

FTC v. Airborne Health, Inc., et al. (Stipulated Final Order 2006)

FTC Advertising Case

2. Are the claims supported?

- All health-related claims require "Competent and Reliable Scientific Evidence"
- Rigorous but flexible approach (look to experts in the field)
- No fixed formula (quality over quantity)
- Generally expect double blind placebo-controlled clinical studies

Substantiation

- Oregano oil extract
- "scientifically proven to prevent/treat colds, flu, hepatitis C, staph, h.pylori, avian flu…"
- In vitro studies not proof of efficacy in humans
- $2.5 million settlement

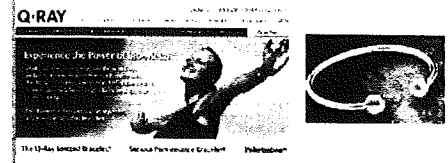
North American Herb and Spice Co, et al. (Stipulated Final Order 2008)

Substantiation

a. Internal Validity

- Control and blinding
- Duration (does effect persist?)
- Dose/response relationship
- Recognized biological mechanism
- Peer review/publication in reputable journal is a plus
- Statistically significant AND clinically meaningful results

Subtantiation



"I've had total knee replacements in both of my knees. .. I was on a cane all the time… Imagine what it must feel like to throw away your cane forever."

FTC v. QT, Inc., Q-Ray et al., (2006)

Substantiation

- "Ionized" bracelet a sham
- $22.5m judgment, (+ up to $87m in consumer refunds -entire net sales)
- No well-controlled double-blind studies
- 8,100 "satisfied" customers not evidence of efficacy (>100,000 requested refunds)
- Mayo clinic study found it no more effective than placebo

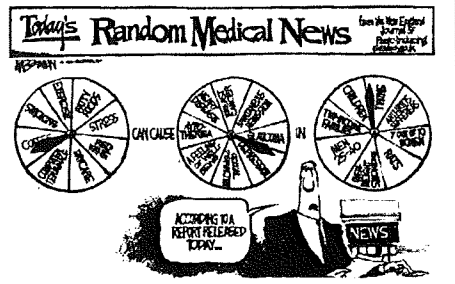
FTC v. QT, Inc., Q-Ray et al., (2006)

Substantiation

b. Context

- Can't evaluate studies in isolation
- Consider all relevant evidence
- Reconcile inconsistent/conflicting results
- Claim may need to be qualified
- Don't make claim if weight of evidence contradicts

Substantiation

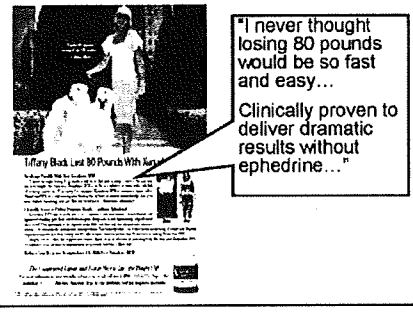


Substantiation

c. Relevance to Product/Claim

- Product and claims have to match the science
- Amount/form of ingredient
- Population studied
- Degree/nature of effect
- Strength of science

Substantiation



"I never thought losing 80 pounds would be so fast and easy...

Clinically proven to deliver dramatic results without ephedrine..."

Substantiation

- Green tea extract, caffeine, bitter orange
- Placebo in one study lost more weight than test group
- Payments for testimonials of up to $20,000 not disclosed
- $8 to 12.8 million in redress

FTC v. Chinery and RTC Research & Development, LLC (stipulated final order)

FTC'S Role

- Enforcement Priorities
  - Health and safety risks
  - Serious diseases (cancer, obesity)
  - Children
  - Outright false claims
  - Widespread or substantial injury

FTC'S Role

- Process and Remedies
  - Federal court actions
  - Broad liability
  - Injunctions & asset freezes
  - Disgorgement/redress
  - Warning letters to copycats

Recent Actions

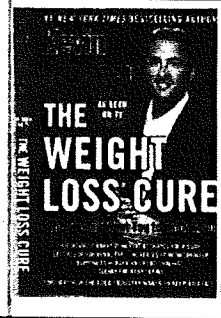
HOODIA

STELLA LABS

- **Suppliers of hoodia gordonii charged**
- **False claims: clinically proven to suppress appetite; reduce caloric intake by 1,000 to 2,000/day; treat obesity**
- **Selling fake hoodia to manufacturers of supplements**

FTC v. David Romeo, Stella Labs, et al. (Complaint 2009)

Recent Actions



- 2004 infomercial ban and $2 million
- Narrow exemption for marketing of books
- 2007 infomercial for book: "easiest, simplest, most effective thing I've ever done...eat whatever you want ...don't gain back the weight"

FTC v. Trudeau (Civil Contempt 2007)

Recent Actions

- Things you must do:
  - Daily injections of prescription drug
  - 500 cal/day diet for 45 days
  - Drink ½ to 1 gallon pure water with coral calcium daily
  - Drink Wu Long tea as directed
  - Walk one hour each day outside
  - Do colonics as directed
  - Eat two organic apples per day
  - Eat organic grapefruits
  - Eat breakfast
  - Eat 6 times per day
  - Finish dinner 3 ½ hours before bed
  - Do a colon cleanse
  - Take extra virgin coconut oil
  - Take saunas as often as possible
  - Plus many other steps...
- Things you must not do:
  - Non non-prescription, over-the-counter, or prescription meds
  - No fast food
  - Limit refined food (white flour; white sugar)
  - No MSG
  - No artificial sweeteners
  - No trans fat
  - No high fructose-corn syrup
  - No nitrites

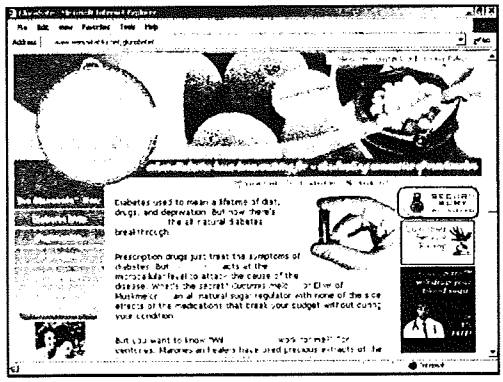
Contempt order includes $5 million and 3-year ban on infomercials for all products, including books

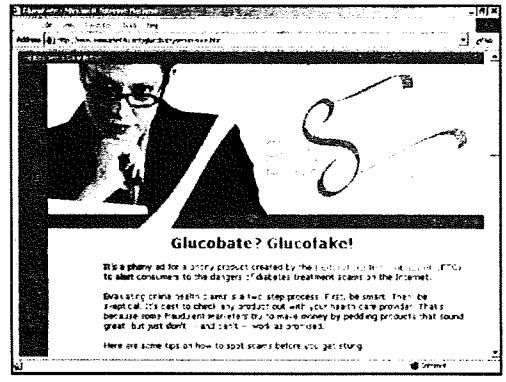
FTC v. Trudeau (Civil Contempt 2007)

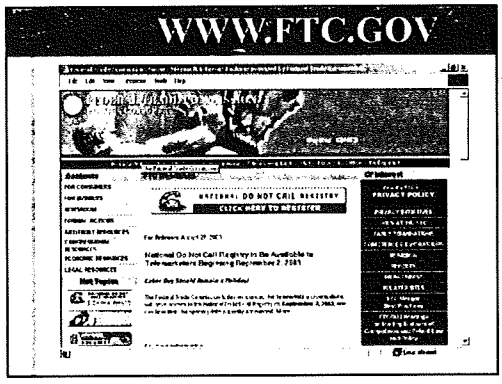
Recent Actions: Criminal Liaison

- FTC Case 2006: Enzyte's "Smiling Bob" ad campaign; also Rogisen and Avlimil
- "Free" samples led to unauthorized auto-shipping
- Criminal Case 2008: DOJ, USPS, FBI, IRS, FDA
- Company and 4 execs convicted on 93 criminal counts of mail fraud, bank fraud, money laundering, obstruction of FTC/FDA cases
- Ordered to forfeit $459,540,000; prison sentences as high as 25 years

Berkeley Premium Nutraceuticals (2008)




Glucobate? Glucofake!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