Food and Drug Administration
Public Hearing

Conventional Foods Being Marketed as “Functional Foods”

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Functional Foods – Public Health Boon or 21st Century Quackery?

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Outline of Presentation

I. Food for thought -- Public policy considerations

II. Regulatory approaches -- food or dietary supplement?

III. CSPI 2002 Petition
I. Food for Thought

• All foods are “functional” foods

• “Functional” foods are not new -- vitamins/minerals have been added to foods for decades

• What, if anything has changed?
Food For Thought

• Foods with novel ingredients can be useful
  – Calcium fortified orange juice
  – Margarine substitute with plant stanol esters
Food for Thought

- However, most products currently on the market do not address chronic disease, but rather are often targeted at minor health problems.

- What role can “functional” foods play in helping consumers address major public health problems?
Products subject of 2000 CSPI Complaint
Food for Thought

• The market place is currently bloated with dubious “functional” foods:
  – Energy drinks
  – Herbal medicines added to beverages/tonics
  – Snacks of low nutritional value

• FDA should use this opportunity to crack down on unauthorized ingredients and claims
AriZona

RX Energy
HERBAL TONIC

AN INVIGORATING BLEND OF GREEN TEA, TROPICAL & CITRUS FRUITS, PANAX GINSENG, SIBERIAN GINSENG, GUARANA, SCHISANDRA, AND VITAMINS A, C & E

THIS PRODUCT IS A FOOD, NOT A DRUG. IT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASES

A REFRESHING ALL NATURAL TONIC™
CERTIFICATE OF PURITY

This is to certify that Dr. Kilmer's Drop-Bust, the great kidney, liver and bladder remedy, is purely vegetable and does not contain any alcohol, mercury, arsenic, arsenic sulphate, opium, strychnine, morphine, alkaloids, potassium, calomel, silicate of magnesia, sulphate of copper, calcium phosphates, and any harmful or Habit-producing drugs. Drop-Bust was discovered through scientific research and study by Dr. Kilmer, who graduated with honors and is now actively engaged in the practice of his profession. With faithful in the successfully fulfilled oath.

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Dr. Kilmer's Drop-Bust is not recommended for children, but if you have
a sick child or otorrhea problem, it will be a real help to administer.
It is a formula that contains the same invisible of drugs, strength and excellence.
This may cause a slight headache Drop-Bust for 10-15 days, if one has not already had one.
When using Dr. Kilmer's Drop-Bust, it is very important not to swallow more than what is prepared
when it is taken.

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II. “Functional” Foods – Regulatory Approaches

• By any definition of the term, functional foods are “foods”

• Accordingly, they must be regulated under the food safety and labeling laws, and not under laws pertaining to dietary supplements (DSHEA)
If it’s a food, it should comply with food law
Foods with added beneficial ingredients can be sold and promoted while complying with food law.
And health claims can be made for both added and natural nutrients
In short, a new regulatory category, favored by some segments of the food industry, is not needed . . .

. . . but FDA regulation of foods with novel ingredients that have physiological effects should be improved
III. 2002 CSPI Petition

A. Food Safety
   – Pre-market notification for “novel” ingredients
   – Defining “novel” ingredients
     » Need to retain nutritive value requirement
     » Other possible elements of definition
   -- Additional safety requirements for “novel” ingredients

B. Label Claims
   – Health Claims
   – Qualified Health Claims
   – Structure/Function Claims
CSPI Petition – Food Safety Elements

• Manufacturers should be required to notify FDA of novel ingredients that are intended to have physiological effects and provide a summary of relevant data

• Because novel ingredients are specifically intended to affect health, they are more likely than other substances to cause adverse effects
CSPI Petition – Food Safety Elements

• Pre-market notification recommended by the GAO in 2000

• Pre-market notification should therefore be required
Food Safety – Novel Ingredients

• FDA should issue guidance on categories of novel ingredients that are subject to, or exempt from, pre-market notification:

  – Subject to notification: Physiologically active substances with no history of use in conventional foods
  
  – Exempt from notification: Vitamins and minerals within safe upper levels
Food Safety – Novel Ingredients

• Authority based on Section 701(a) of the FDCA – Issue regulations for efficient enforcement of the Act, and Sections 402, 403 and 409

• GAO recommended that FDA seek new legislation
Food Safety – Novel Ingredients

• Pre-market notification will help ensure that all market entry decisions are made in full compliance with the law -- Pre-Market notice proposal for bioengineered foods, 66 Fed Reg 4706 (2001)
Food Safety – Novel Ingredients

• How should a “novel ingredient” be defined?

• Novel ingredients must provide “nutritive value”

• FDA’s criteria for nutritive value are flexible
Food Safety – Novel Ingredients – FDA Criteria for Nutritive Value


– Substance can assist in the functioning of metabolic processes necessary for the normal maintenance of life, 59 Fed. Reg. 395 at 407 (1994) (Discussing role of dietary fiber on normal functioning of the body)
Possible criteria for defining novel ingredients subject to pre-market notification

• Must primarily provide taste, aroma, or nutritive value or otherwise affect the characteristics of the food

• But, are added to foods for the express or implied purpose of affecting physiology
Possible Criteria for Novel Ingredients

• Must meet the FDA’s fortification policy

• Should generally not be added to foods of low nutritional value
Food Safety at Risk?

• IFT has some very different ideas for new “functional” ingredients. They would be:

  “biologically active components that impart desirable physiological effects.”

Quoting IFT Report
Food Safety at Risk?

- Nutritive value would NOT be required
- The distinction between foods and drugs would be eviscerated
Food Safety at Risk?

• Recommendations to permit the addition of non-nutritive substances to foods, and to make health-related claims for purported physiological effects, strike at the heart of the FDCA

• IFT Committee heavily influenced by industry representatives and consultants
Food Safety at Risk?

• Where would we draw the line?

• Would a manufacturer be allowed to add willow bark to iced tea to alleviate headaches?

• Congress drew a distinction between foods and drugs for a good reason
Additional safety issues – Warnings/Packaging

• If use of a novel substance is allowed, FDA should specify safety related labeling requirements including limits on consumption, allergies, and use by vulnerable groups including children, pregnant women and the elderly.

• FDA should specify packaging requirements when necessary to ensure safe use (e.g., individual servings, child resistant packaging).
Additional Safety Issues Post - Marketing

• FDA should require manufacturers to conduct post-marketing surveillance when appropriate
• Reports of adverse effects must be reported to the FDA on a timely basis
• Health impact studies should be conducted and made publicly available
2002 CSPI Petition – Claims Elements

Current types of Claims:

- Significant Scientific Agreement
- Authoritative Statements
- Qualified Health Claims
- Structure/Function Claims
- Nutrient Content Claims
- Claims for medical foods
- Foods for special dietary use
Qualified Health Claims

- CSPI believes QHCs are not authorized for foods

- Unlike DSHEA, Congress provided a specific statutory standard “SSA” for food health claims

- *Pearson v. Shalala* was not decided in the context of foods
Qualified Health Claims

• NLEA legislative history provides a solid basis for stricter standards for foods

• Foods and supplements are consumed for different reasons, by different groups of consumers, and in different forms. Foods should not be regulated as supplements
Qualified Health Claims

• FDA’s own study on QHC’s shows that consumers do not understand them

• QHC’s should not be authorized unless and until consumer studies show that they are not misleading
Structure/Function Claims

• Congress provided for S/F claims for foods as an exemption to the definition of a drug

• All products making S/F claims (except foods) are drugs
Structure/Function Claims

• The purpose was to cover products like “Slenderizers” in drug definition, even if no disease claims were made.

• The purpose was not to allow drug-like claims for foods.
Structure/Function Claims

• “Common sense” definition of food -- Food is primarily consumed for “taste, aroma, or nutritive value”
  » Nutrilab v. Schweiker (1983)

• Physiological effect is secondary (coffee, prune juice)
Structure/Function Claims

• Claims for “functional” foods are intended to affect health; the FDA should be notified prior to marketing

• FDA could develop a list of claims it considers permissible and that do not require notification
Structure/Function Claims

• Legal Authority for pre-market notification:
  - Section 701(a) – Efficient enforcement of the Act
  - Sections 403 and 201(n)

• GAO recommended that FDA seek legislation
Structure/Function Claims – How should they be evaluated?

- Studies show consumers don’t distinguish between S/F and health claims

- Thus, the level of evidence required for both a health claim and a S/F claim should be “Significant Scientific Agreement”
Structure/Function Claims – How should they be evaluated?

IFT approach only requires that:

“a substantial body of evidence exists for plausibility.”


• IFT approach would roll back enforcement standards
Structure/Function Claims – Additional Requirements

- Nutrient disqualifying levels for health claims should apply to S/F claims

- Jelly Bean rule should apply to S/F claims
Need for Disclaimers?

• 2002 GAO report and CSPI petition discuss disclaimer requirement

• No need for disclaimers if FDA sets and enforces substantiation requirements

• 2004 – Studies show DSHEA disclaimer is ineffective

  » Eggers and Fishhoff, *Journal of Public Policy and Marketing*, Vo. 23(1) Page 16
In summary . . .

- Promoting food ingredients on the basis of physiological effects is a serious public health matter

- Regulatory policy should be proportional to the seriousness of the issue
In summary . . .

- IFT approach would roll back food safety and label claim rules in the name of creating a new category of food products

- Let’s start talking less about “functional foods,” a marketing term, and more about how “novel ingredients” should be regulated
In summary . . .

- Foods with novel ingredients, meeting FDA food additive and labeling rules, are being successfully marketed under existing law -- no new regulatory category is needed
In summary . . .

- While existing laws are adequate, the FDA needs to update its enforcement policies to keep control of the marketplace.

- Novel substances with physiological effects call for pre-market notification of ingredients and Structure/Function claims.
Let’s Not Go Here!
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