

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

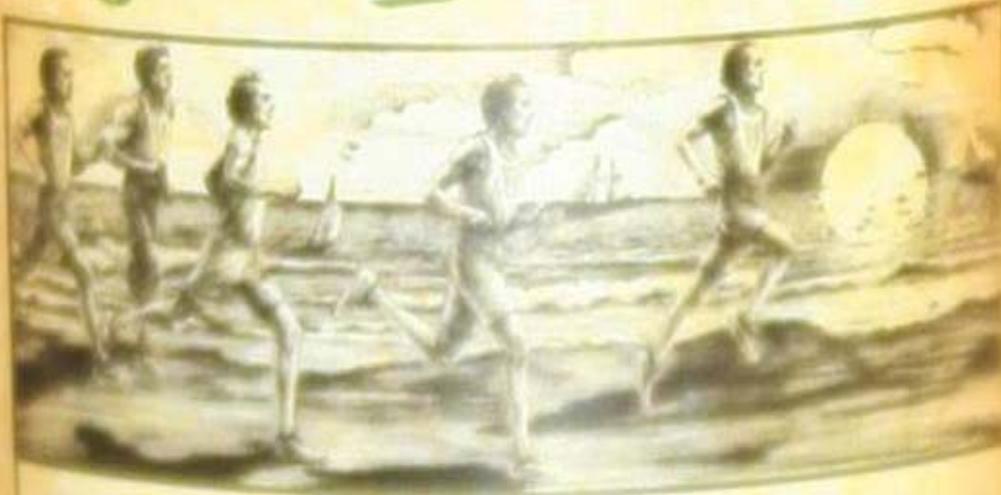
Food for Thought

- 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?

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.



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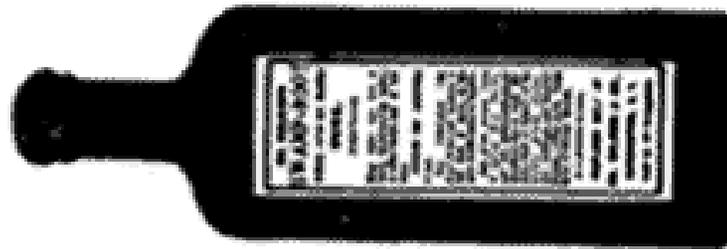
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James Leavelle

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JAMES W. ELMER, being master of the firm of Dr. Elmer & Co., of the City of Binghamton, County of Broome, State of New York, being SWAMP-ROOT, do hereby and say that the guarantee of purity of Swamp-Root, as described in the foregoing certificate, is in all respects true.

Subscribed and sworn to:
witness on April 20, 1903.

James W. Elmer



James W. Elmer
James W. Elmer

Dr. Elmer's Swamp-Root is not recommended for medicinal use if you have kidney, liver or bladder trouble, it will be found that it contains no such. Swamp-Root contains the same amount of purity, strength and medicinal value that there is a single ounce of Swamp-Root in the world. If you have not already had it, write asking for it, Elmer & Co., Binghamton, N. Y., be sure to mention reading this guarantee when you order.

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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



The image shows the packaging for Benecol dietary supplement. The top left features a green square with a white stylized 'B' logo. To the right, the word 'Benecol' is written in a large, dark serif font, with 'New!' in red script above it. Below the brand name, 'dietary supplement' is written in a smaller, green, lowercase font. The central text reads 'promotes healthier Lower Cholesterol levels*'. Below this, it says 'As Part of Your Healthy Lifestyle'. On the left, there is a '21' in a green font next to a small icon of a spread, with 'INDIVIDUAL SERVINGS' and '© Pareve' below it. The net weight is listed as 'NET WT. 5.9 OZ. (168g)'. At the bottom left, a small box contains a disclaimer: '* THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.' The bottom right section features a photograph of a slice of bread with a pat of butter and a dusting of red powder, with the text 'dietary supplement in a spread form smooth creamy taste' overlaid.

New!
Benecol[®]
dietary supplement

promotes healthier
Lower Cholesterol
levels*

As Part of Your
Healthy Lifestyle

21  ^{© Pareve}
INDIVIDUAL SERVINGS

NET WT. 5.9 OZ. (168g)

* THIS STATEMENT HAS NOT BEEN EVALUATED BY THE
FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE,
TREAT, CURE OR PREVENT ANY DISEASE.

dietary supplement in a
spread form smooth
creamy taste

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

Health News

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POTASSIUM**

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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 effects¹⁷

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 be useful in reducing risk of chronic disease 55 Fed. Reg 5176 at 5177 (1994) (General Rules for Health Claims).
- 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.”

FDA Fed. Reg. Notice
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 Report , page 27 (2005)

- 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 Fishhhoff, *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

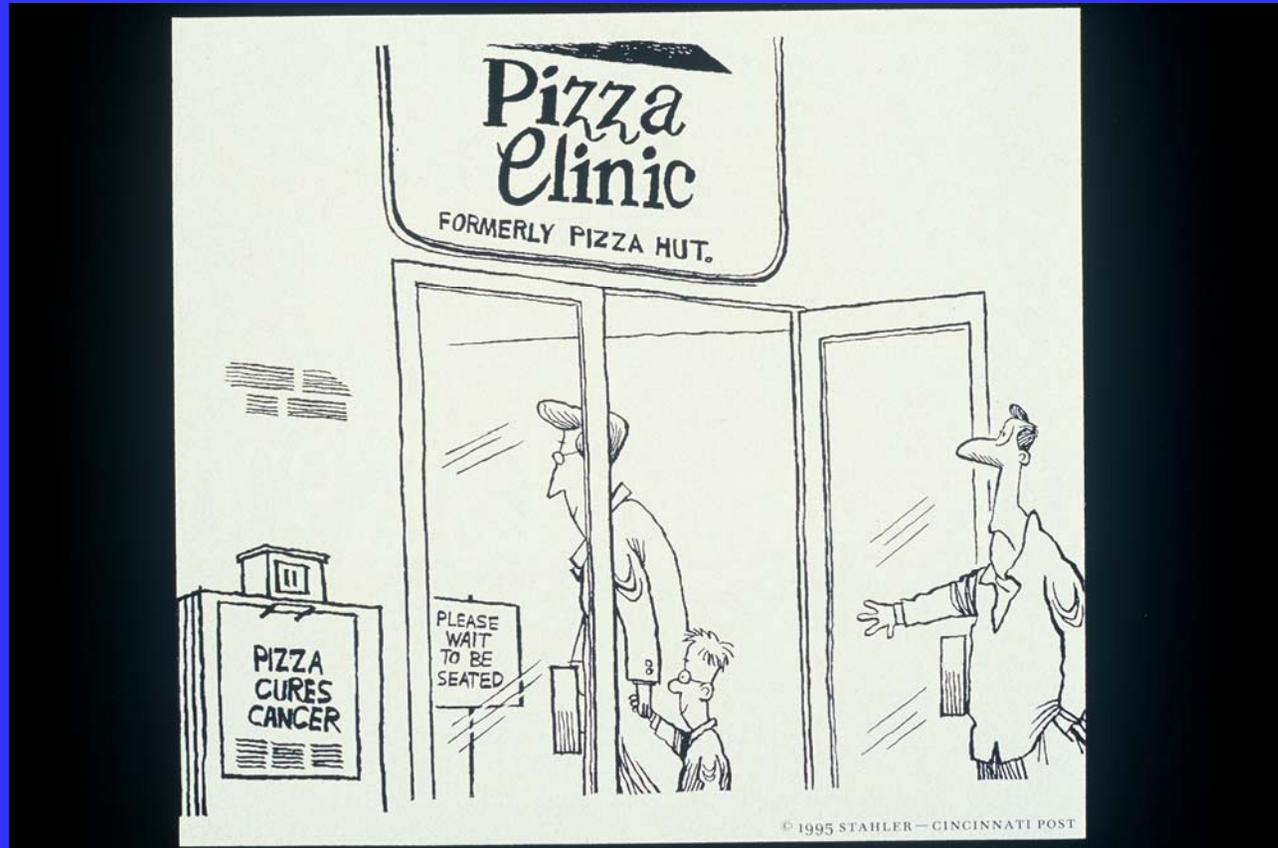
In summary . . .

- 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!



www.cspinet.org

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