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# Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims

Brenda M. Derby, Ph.D. & Alan S. Levy, Ph.D.  
Food & Drug Administration  
Office of Regulations & Policy  
November 17, 2005



# Information Objective

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**Assess effectiveness of different ways to communicate the level of scientific support for health claims on food labels**



# Operational Definitions

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- **Health claim:** Statement that “X may reduce the risk of Y”
- **Unqualified health claim condition:** statement above for each of 4 diet-disease relationships
- **Disclaimer conditions:** health claim accompanied by a disclaimer under one of the 4 disclaimer schemes



# FDA Study Health Claim Statements

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- Calcium may reduce the risk of osteoporosis.
- Omega-3 fatty acids may reduce the risk of heart disease.
- A diet high in selenium may reduce the risk of cancer.
- The antioxidant lycopene may reduce the risk of certain cancers, including prostate cancer in men.



# FDA Study

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- **Examine 4 possible “disclaimer schemes” for qualifying health claim statements on food labels**
- **Disclaimer schemes intended to convey three levels of qualification (B>C>D)**
- **Focus is communication effectiveness, not the health claims themselves**



# Four Disclaimer Schemes

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- **Point-Counterpoint (claim/disclaimer)**
- **Embedded (disclaimer/claim)**
- **Text Report Card**
- **Graphic Report Card**



# Point-Counterpoint Scheme

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**“Calcium may reduce the risk of osteoporosis. The scientific evidence is promising but not conclusive.”**



# Embedded Scheme

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**“Limited and inconclusive scientific evidence suggests that omega-3 fatty acids may reduce the risk of heart disease.”**



# Text Report Card Scheme

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**“A diet high in selenium may reduce the risk of cancer. FDA evaluated the scientific evidence and gave it a “C” rating, based on a scale from A (strongest evidence) to D (weakest evidence).”**

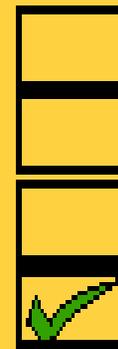


# Graphic Report Card Scheme

The antioxidant lycopene may reduce the risk of certain cancers, including prostate cancer in men.

## FDA Rating of Scientific Evidence

- A. Strong Evidence
- B. Moderate Evidence
- C. Some Evidence
- D. Little Evidence



NET WT. 1lb. 9.75oz. (730g)



# Experimental Design and Methods

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- Shopping mall-intercept experiment
- Sample of 1,920 adults
- Each respondent sees one product with a disclaimer and one product with a control label
- Each respondent randomly assigned to a disclaimer/control label combination to control bias



# Four Experimental Labels

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Represent a range of scientific certainty:

- Orange Juice/Calcium-Osteoporosis
- Tuna/Omega 3-Heart Disease
- Eggs/Selenium-Cancer
- Spaghetti Sauce/Lycopene-Cancer



# Orange Juice: No Claims Control

**GATOR**  
Orange Juice



100% Pure Florida Squeezed  
Orange Juice. Not From Concentrate.

64 FL OZ (2 QT) 1.89L PASTEURIZED

**GATOR**  
Orange Juice

## Nutrition Facts

Serving Size 8 fl oz (240 mL)  
Servings Per Container varies

Amount Per Serving

Calories 110

	% Daily Value*
Total Fat 0	0%
Sodium 0mg	0%
Potassium 450mg	13%
Total Carbohydrate 27g	9%
Sugars 24g	
Protein 2g	

Vitamin C 120%	Calcium 35%
Vitamin D 25%	Thiamin 10%
Niacin 2%	Vitamin B6 4%
Folate 15%	Magnesium 6%

Not a significant source of dietary fiber,  
Vitamin A and iron.

\*Percent Daily Values are based on a 2,000  
calorie diet.

Ingredients: 100% Pure squeezed  
Pasteurized Orange Juice and FruitCal  
(Calcium Hydroxide, Malic Acid and  
Citric Acid)



# Tuna: Embedded, Level B Claim

**NEW! NO DRAIN PACKAGE!**

# BLUESEA

**FLAVOR FRESH POUCH**

## LIGHT TUNA IN WATER

**180 MG  
OMEGA-3  
FATTY ACIDS**

Fresher tasting  
Firmer texture  
No draining!

Promising but not  
conclusive scientific  
evidence suggests that  
omega-3 fatty acids  
may reduce the risk of  
heart disease.



# BLUESEA

**FLAVOR FRESH POUCH**  
**LIGHT TUNA**  
IN WATER

### Nutrition Facts

Serving Size 1 pouch (3 oz/85g)  
Servings Per Pouch: 1

Amount Per Serving		
Calories 105	Calories from fat 15	% Daily Value*
<b>Total Fat</b> 1.5g		2%
Saturated Fat 0g		0%
<b>Cholesterol</b> 40mg		13%
<b>Sodium</b> 380mg		16%
<b>Total Carbohydrate</b> 27g		9%
Dietary Fiber 0g		0%
Sugars 24g		
<b>Protein</b> 23g		42%
Vitamin A 0%	Vitamin C 0%	
Calcium 0%	Iron 0%	
Niacin 53%	Vitamin B6 15%	

\*Percent Daily Values are based on a 2,000 calorie diet.

INGREDIENTS: LIGHT TUNA, WATER,  
VEGETABLE BROTH, SALT,  
PHYOPHOSPHATE



# Eggs: Text Report Card, Level C Claim



Great Taste!

**Benson's**

**Benson's Farm Fresh Eggs**  
High in selenium

A diet high in selenium may reduce the risk of cancer. FDA evaluated the scientific evidence and gave it a "C" rating, based on a scale from A (strongest evidence) to D (weakest evidence).

**12 Extra Large Eggs**



## Nutrition Facts

Serving Size 1 egg (56g)  
Servings Per Container 12

Amount Per Serving	
Calories 80	Calories from fat 45
% Daily Value*	
Total Fat 5g	8%
Saturated fat 1.5g	8%
Cholesterol 240mg	79%
Sodium 70mg	3%
Total Carbohydrate 1g	0%
Protein 7g	15%

Vitamin A 8%	Vitamin C 0%
Calcium 2%	Iron 4%
Selenium 24%	

Not a significant source of dietary fiber, Vitamin A and iron.

\*Percent Daily Values are based on a 2,000 calorie diet.



# Spaghetti Sauce: Graphic Report Card, Level D Claim

**GARDEN STYLE**  
Tastes Homemade!

**BUENA BUENA!**



**FINE SPAGHETTI SAUCE**

**20 mg lycopene**

**The antioxidant lycopene may reduce the risk of certain cancers, including prostate cancer in men.**

**FDA Rating of Scientific Evidence**

A. Strong Evidence	<input type="checkbox"/>
B. Moderate Evidence	<input type="checkbox"/>
C. Some Evidence	<input type="checkbox"/>
D. Little Evidence	<input checked="" type="checkbox"/>

**NET WT. 1lb. 9.75oz. (730g)**

**BUENA BUENA!**  
GARDEN STYLE  
**FINE SPAGHETTI SAUCE**



**Nutrition Facts**

Amount Per Serving	% Daily Value*
Total Fat 5g	8%
Sat. Fat 1.5g	8%
Cholesterol 0mg	0%
Sodium 450mg	19%
Total Carbohydrate 19g	6%
Dietary Fiber 3g	12%
Sugars 12g	
<b>Protein 2g</b>	
Vitamin A 10%	Vitamin C 2%
Calcium 2%	Iron 4%

Serving Size 1/2 cup (120ml)  
Servings per Container about 6  
Calories 130  
Calories from Fat 45  
\*Percent Daily Values are based on a 2,000 calorie diet.

**INGREDIENTS:** TOMATO PUREE (WATER, TOMATO PASTE), MUSHROOMS, CORN SYRUP, DICED TOMATOES IN TOMATO JUICE, VEGETABLE OIL (CORN AND/OR COTTONSEED AND/OR CANOLA), SALT, DEHYDRATED ONIONS, GARLIC, SPICES (BASIL, OREGANO, SPICE), CITRIC ACID, FLAVORING AND DEHYDRATED PARSLEY



# Four Performance Measures of Label Impacts

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- Perceived strength of scientific evidence
- Perceived likelihood of claimed health benefit
- Perceived likelihood of other health benefits
- Perceived importance of product as part of a healthy diet



# Four Performance Measures of Label Impacts

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- **Perceived strength of scientific evidence**
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- Perceived likelihood of other health benefits
- Perceived importance of product as part of a healthy diet



# Perceived Strength of Scientific Evidence Measure

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- 7-point scale from “very uncertain” to “very certain”
- How certain is the scientific evidence that eating foods that contain (nutrient) will reduce the risk of (health condition)?



# Four Performance Measures of Label Impacts

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- Perceived strength of scientific evidence
- **Perceived likelihood of claimed health benefit**
- **Perceived likelihood of other health benefits**
- Perceived importance of product as part of a healthy diet



# Claim-Relevant and Other Health Benefit Measures

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- 7-point scale from “not at all likely” to “very likely”
- How likely is it that eating this food as a regular part of one’s diet would:
  - Reduce the risk of having a heart attack?
  - Reduce the risk of having high blood pressure?
  - Reduce the risk of getting cancer?
  - Reduce the risk of getting osteoporosis (sometimes called brittle bones)?



# Four Performance Measures of Label Impacts

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- Perceived strength of scientific evidence
- Perceived likelihood of claimed health benefit
- Perceived likelihood of other health benefits
- **Perceived importance of product as part of a healthy diet**



# Health Importance Measure

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- 7-point scale from “not at all important” to “very important”
- How important would this food be as part of a healthy diet for you?



# Control Conditions To Assess Communication Effectiveness

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- No claims
- Unqualified health claim statement
- Nutrient declaration/content claim only
- Unqualified health claim statement without “may”
- “Full Information” about nutrient/disease relationship



# Communication Effectiveness Performance Standards

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- Identified 3 performance standards to assess the effectiveness of the disclaimer schemes:
  - Linear effect of disclaimer levels
  - Effect of disclaimers on perception of scientific certainty
  - Effect of disclaimers on perceptions of product health benefits



# Do disclaimers convey decreasing levels of scientific support?

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- The perceived strength of science conveyed by a disclaimer should decrease significantly as the disclaimer says the evidence is weaker
- Data Analysis: Look for significant linear effect of disclaimer level on the perceived strength of science measure (i.e.,  $B > C > D$ )



# Is perceived scientific certainty affected when a disclaimer is present?

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- Disclaimer should counteract the effect of an unqualified health claim statement on perceived scientific certainty
- Analysis: Compare effect of (1) no claim vs. unqualified health claim (“Health Claim Effect”) and (2) unqualified claim vs. appropriate disclaimer conditions (“Disclaimer Effect”)



# Are inferences about the health benefits of a product affected?

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- Inferences made about the product should be consistent with the effects of disclaimers on perceived scientific certainty
- Analysis: Compare the effects of health claims and disclaimers on product perception measures



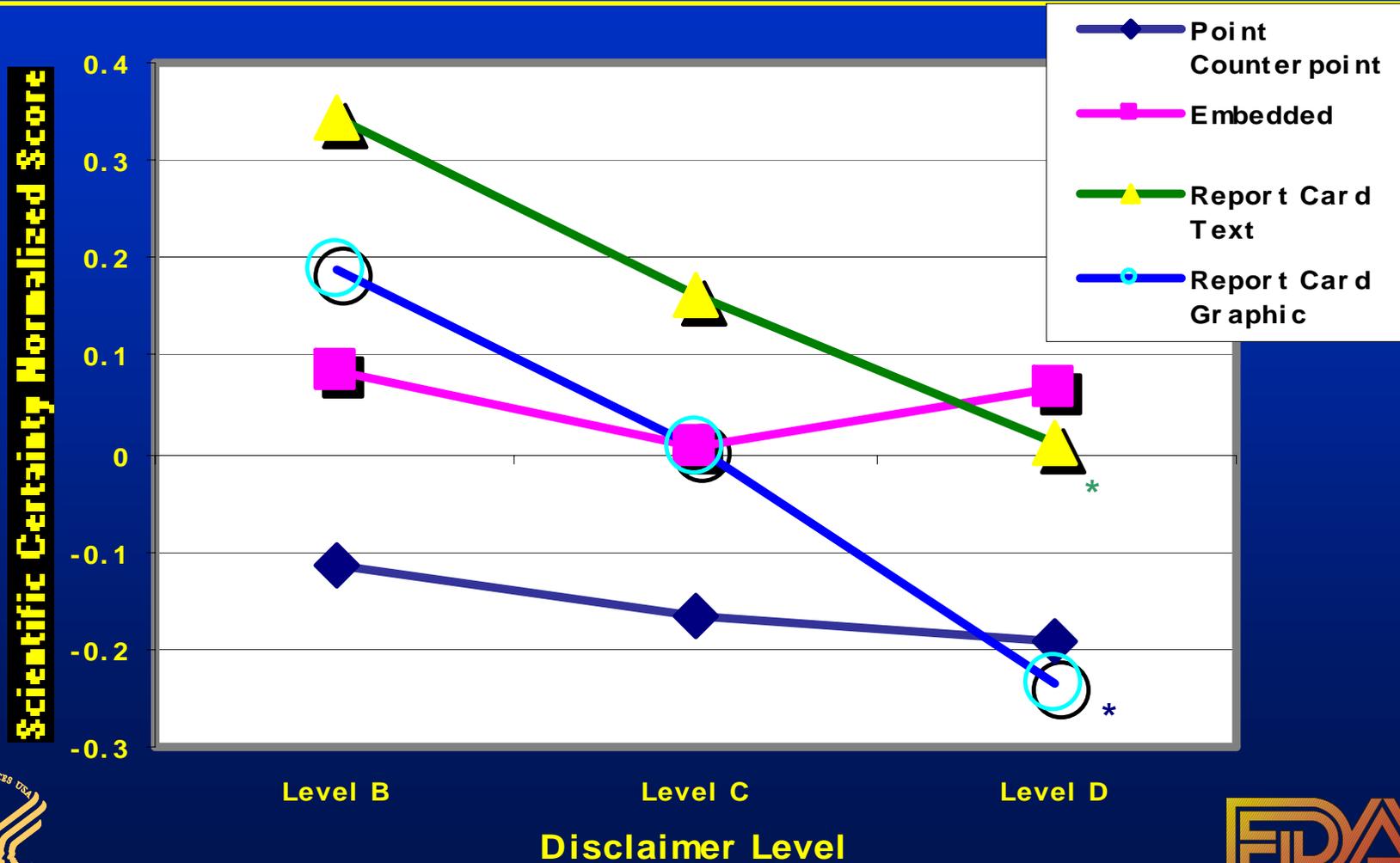
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# RESULTS



# Effect of Disclaimer Level by Disclaimer Scheme



\* p < .02



# Linear Effect of Disclaimers

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- Point-Counterpoint and Embedded Schemes did not communicate different levels of scientific certainty
- Report card ratings resulted in correct linear pattern (B > C > D)



# Analysis Note

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- **Point/Counterpoint and Embedded disclaimer schemes failed to correctly convey the intended levels of scientific support**
- **Therefore, results on Health Claim And Disclaimer Effects that follow based only on respondents who saw Text Report Card and Graphic Report Card disclaimers**



# Key Effects on Product Perceptions

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- **Health Claim Effect: Comparison of No Claim and Unqualified Health Claim conditions**
- **Disclaimer Effect: Comparison of Disclaimer and Unqualified Health Claim**



# Effects on Scientific Certainty

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- **Health Claim Effect**—Significantly greater certainty when an unqualified health claim present, esp. for less familiar nutrients
- **Disclaimer Effect**—Presence of the appropriate disclaimer effective only for D level claim (lycopene); Level B and C claims (omega-3, selenium) more positive with a disclaimer



# Perceived Relevant Health Benefits

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- **Health Claim Effect**—Significantly more positive about health benefit with the health claim present; again more so for less familiar nutrients
- **Disclaimer Effect**—Presence of the disclaimer did not affect the perceived health benefit



# Other Perceived Health Benefits

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- **Health Claim Effect**—When a health claim is present, perceive other benefits for 2/4 claims; greatest for the D level claim
- **Disclaimer Effect**—Presence of the disclaimer no significant effect on perceptions of other health benefits compared to unqualified health claim



# Perceived Health Importance

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- **Health Claim Effect**—Only significant effect of presence of a health claim for D level (lycopene) claim
- **Disclaimer Effect**—Presence of the disclaimer had no significant effect on perceived health importance compared to relevant unqualified health claim



# Effect of Omitting “may”

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- Unexpected reversal for perceived health importance--significantly more negative if claim stated without “may” (a “boomerang effect”)
- Exception--B level claim (omega-3/tuna), where more positive ratings when “may” omitted for scientific certainty and “other benefits”



# Unqualified Health Claim Statement v. Nutrient Declaration/Content Claim

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- For familiar calcium/osteoporosis claim, nutrient claim comparable effects as the health claim
- Stronger impacts for least familiar health claims regarding scientific certainty, relevant health benefit and health importance compared to the nutrient declaration/content claim



# Effects of “Full Information”

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- Reading one page summary resulted in greater perceived scientific certainty for A and B level health claims
- Increasingly negative summaries (C and D level claims) resulted in ratings comparable to those of respondents seeing the unqualified health claim



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# Conclusions



# Do Disclaimers Work?

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- Text only disclaimers were unsuccessful at communicating different levels of scientific support
- The report card rating schemes conveyed levels more successfully, but also created incorrect inferences—particularly when disclaimers graded claims as “B” or “C”



# Health Claim Effects

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- Health claims create more positive impressions of a food product, and disclaimers do not change this effect
- Health claims often have stronger effects when the relationship mentioned is less familiar to consumers



# Other Effects

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- **Consumers’ prior beliefs matter—for example, a claim may be seen as too strong, causing a “boomerang effect”**
- **Any information, even highly qualified, may increase confidence in the potential health benefits**



# Further Information

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**Full report available online:**

**[http://www.fda.gov/OHRMS/dockets/  
dockets/03N0496/03N-0496-rpt0001.pdf](http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf)**

