

CS-IFT

“Today’s Consumers – Tomorrow’s Labels”

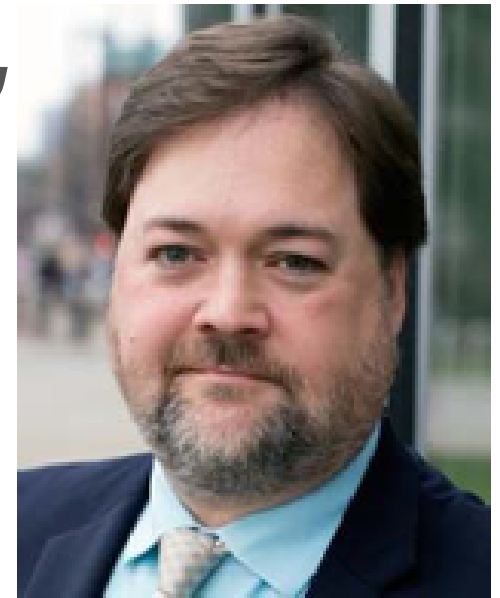
Dr. Darin Detwiler, LP.D

College of Professional Studies

Regulatory Affairs of Food & Food Industry



Northeastern University



Definition of Labeling



1938 FD&C Act

1966 FPLA

21 C.F.R. § 101

*Federation of
Homemakers v. Butz*
(1972)

1990 NLEA

2004 FALCPA

21 C.F.R. § 101.11

*GMA et al. v. Sorrell
et al.* (2015)

*Segovia et al. v.
Vitamin Shoppe Inc.*
(2015)

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Labeling is defined as ...
“all labels and other written, printed, or
graphic matter upon any article...or
accompanying such article.”

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FEDERAL FOOD, DRUG, and COSMETIC ACT

Acronym	FFDCA, “FD&C Act”
Citations	<i>Public Law: 75-717</i>
	<i>Statute: 52 US Stat. 1040</i>
Codification	21 U.S.C. § 301 et seq
Legislative History	Signed into law by President FD Roosevelt, June 25, 1938

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Wheeler-Lea Amendment	
Citation	<i>Statute:</i> 52 US Stat. 111, 114
Codification	15 U.S.C. 52658
Legislative History	1938



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FAIR PACKAGING AND LABELING ACT	
Acronym	FPLA
Citations	<i>Public Law: 89-755</i>
	<i>Statute: 80 US Stat. 1296</i>
Codification	15 U.S.C. Ch. 39. §§ 1451 et seq
Legislative History	Signed into law by President LB Johnson, November 3, 1966



The ***Fair Packaging and Labeling Act*** applies to labels on many consumer products. It requires the label to state:

- The identity of the product;
- The name and place of business of the manufacturer, packer, or distributor; and
- The net quantity of contents.

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...to prevent unfair and deceptive trade practices, and to provide consumers with accurate information regarding the quantity and value of products.

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- The identity of the product;
- The name and place of business of the manufacturer, packer, or distributor; and
- The net quantity of contents.

Federal Trade Commission (FTC) regulations of interest in 16 CFR:

Part 500 -main requirements for labeling.

Amended 1994 to incorporate the metric labeling requirement

Part 501 covers exceptions for a few odds and ends

Part 502 covers other aspects of labels like "cents off," "economy size," etc.

Part 503 includes guidance on how to decide whether an article is covered by the FTC regulations, with lists of examples of what are and aren't "consumer commodities."

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Part 500 - main requirements for labeling.

Amended 1994 to incorporate the metric labeling requirement

§ 500.26 Representations of servings, uses, applications.

(c) If there exists a voluntary product standard promulgated pursuant to the procedures found in 15 CFR part 10, by the **Department of Commerce**, quantitatively defining the meaning of the terms servings, use, or application with respect to a particular consumer commodity, then any label representation as to the number of servings, uses, or applications in such packaged consumer commodity shall correspond with such quantitative definition.

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21 C.F.R. Part 101

Location of FDA's labeling regulations.

§ 101.1 – Principal display panel

§ 101.2 – Information Panel

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Federation of Homemakers v. Butz (1972)

466 F.2d 462 (1972)

FEDERATION OF HOMEMAKERS v. Earl L. BUTZ et al., Appellants.

United States Court of Appeals, District of Columbia Circuit.

Argued June 6, 1972.

Decided August 18, 1972.

The Court applied an “ordinary consumer” test when assessing whether meat labeling is false or misleading, in this case – “All Meat” labeling for foods with less than 100% all meat.”

Do the words "All Meat" mean to an ordinary consumer, as distinguished from an expert, that a frankfurter in a package on which these words appear contains 85 percent meat and other components, and not 81½ percent meat and other components? We think the answer to the question is plain, that the words do not convey that meaning and distinction, and that the Secretary could not reasonably conclude that they do. As employed, therefore, the "All Meat" label is misleading and deceptive.

The district court ordered the Secretary to discontinue the use of the "All Meat" label within six months

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Nutrition Labeling and Education Act	
Acronym	NLEA
Citations	<i>Public Law: 101-535</i>
Codification	21 U.S.C. Ch. 9 § 301
Legislative History	Signed into law by President George H. W. Bush, November 8, 1990



NLEA enables the FDA to require nutrition labeling of most foods regulated by the Agency; and to require that all nutrient content claims (for example, 'high fiber', 'low fat', etc.) and health claims meet FDA regulations.

The act did not apply to restaurants.

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- Food Labeling:
 - Establishment of Date of Application
 - Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label
 - Reference Daily Intakes and Daily Reference Values
 - Serving Sizes
 - Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food
 - Labeling Statements on Foods for Special Dietary Use
- Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term
 - Labeling: Use of Nutrient Content Claims Food for Butter
- State Enforcement Provisions of The Nutrition Labeling and Education Act of 1990
- State Petitions Requesting Exemption from Federal Preemption
- Certain Misbranding Sections of the FD&C Act
- Food Labeling; General Requirements for Health Claims for Food
- Food labeling: Health claims and Label Statements
- Regulatory impact Analysis of the Final Rules to Amend the Food Labeling Regulations

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Food Allergen Labeling and Consumer Protection Act	
Acronym	FALCPA
Citations	<i>Public Law: 108-282, Title II</i>
Codification	21 U.S.C. Ch. 9 § 301
Legislative History	Signed into law by President George W. Bush, 2004



FALCPA requires all food labels in the United States to list ingredients that may cause allergic reactions, and took effect January 1, 2006. The purpose of this act was to prevent manufacturers from using misleading, uncommon, or confusing methods to label their ingredients.



Milk



Eggs



Fish



Crustacean Shellfish



Tree Nuts



Peanuts



Wheat



Soya

Definition of Labeling

21 CFR § 101.11 –

NUTRITION LABELING OF STANDARD MENU ITEMS IN COVERED ESTABLISHMENTS

1938 FD&C Act

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FDA Final rule as of December 1, 2014

20 or more locations within a chain doing business (even franchises) and offering for sale substantially the same menu items.

Number of calories (in context with recommended total daily caloric intake)

Other, written nutrition information



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GMA et al. v. Sorrell et al. (2015)



Vermont's Act 120 was signed on May 8, 2014 and will be enforceable effective July 1, 2016 requires that "food [intended for human consumption] offered for sale by a retailer" after the Act's effective date "be labeled as produced entirely or in part from genetic engineering if it is a product: (1) offered for retail sale in Vermont; and (2) entirely or partially produced with genetic engineering." 9 V.S.A. § 3043(a).

In *GMA et al. v. Sorrell et al.* plaintiffs' complaint challenges Act 120's requirement that certain manufacturers and retailers identify whether raw and processed food sold in Vermont was produced in whole or in part through genetic engineering and which prohibits manufacturers from labeling or advertising GE foods

Genetic engineering ("GE") is defined as "a process by which a food is produced from an organism or organisms in which the genetic material has been changed"

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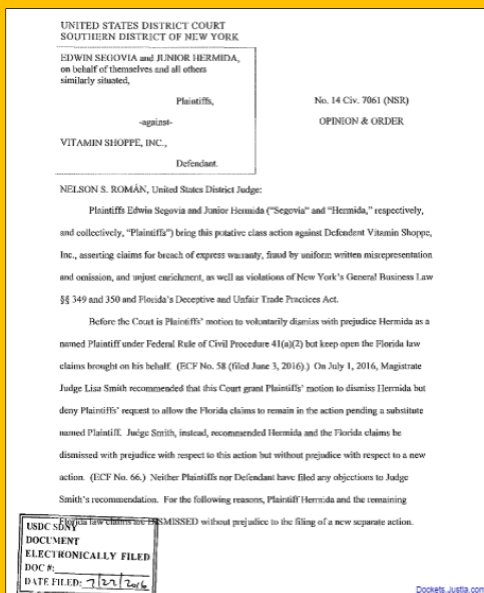
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Segovia et al. v. Vitamin Shoppe Inc. (2015)



A false labeling class action lawsuit, alleging that the claims made on several of its dietary supplements and protein products are false.

Plaintiffs allege that Vitamin Shoppe “knowingly employs a common scheme of under-dosing the ingredient Aminogen in all of the products and falsely claiming that lactase aids in the absorption and digestion of protein.” Segovia and Florida resident Hermida say that these “claims are false and misleading.”

“[Vitamin Shoppe], unapologetically and with no remorse, boasts about the inclusion of Aminogen in the products, but then under-doses it in the formula to make the ingredient useless,” they allege in their Vitamin Shoppe class action lawsuit.

In addition, they allege that Vitamin Shoppe also makes “false claims regarding the function of lactase in the body.”

Recent Revisions of the Nutrition and Supplement Facts Labels

Nutrition Facts		Nutrition Facts	
Serving Size 2/3 cup (55g) Servings Per Container About 8		8 servings per container Serving size 2/3 cup (55g)	
Amount Per Serving		Amount per serving	
Calories 230	Calories from Fat 72	Calories 230	
% Daily Value*		% Daily Value*	
Total Fat 8g	12%	Total Fat 8g	10%
Saturated Fat 1g	5%	Saturated Fat 1g	5%
Trans Fat 0g		Trans Fat 0g	
Cholesterol 0mg	0%	Cholesterol 0mg	0%
Sodium 160mg	7%	Sodium 160mg	7%
Total Carbohydrate 37g	12%	Total Carbohydrate 37g	13%
Dietary Fiber 4g	16%	Dietary Fiber 4g	14%
Sugars 1g		Total Sugars 12g	
Protein 3g		Includes 10g Added Sugars	20%
Vitamin A	10%	Protein 3g	
Vitamin C	8%	Vitamin D 2mcg	10%
Calcium	20%	Calcium 260mg	20%
Iron	45%	Iron 8mg	45%
		Potassium 235mg	6%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.		* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	
	Calories: 2,000 2,500		
Total Fat	Less than 65g 80g		
Sat Fat	Less than 20g 25g		
Cholesterol	Less than 300mg 300mg		
Sodium	Less than 2,400mg 2,400mg		
Total Carbohydrate	300g 375g		
Dietary Fiber	25g 30g		

Updated Serving Sizes

Larger Type

Updated Daily Values

New: Added Sugars

Actual Amounts Declared

New: Footnote



Manufacturers will need to use the new label by **July 26, 2018**.

However, manufacturers with less than \$10 million in annual food sales will have an additional year to comply.

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Responsible Corporate
Officer Doctrine

A.K.A.:
"R.C.O. Doctrine"

From *U.S. v. Park* (1975)

The responsible corporate officer doctrine imposes strict liability on corporate officers based solely on their area of responsibility within the corporation, regardless of their knowledge of the underlying criminal activity or their participation in it.

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Safe Handling Instructions

This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

-  Keep refrigerated or frozen. Thaw in refrigerator or microwave.
-  Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.
-  Cook thoroughly.
-  Keep hot foods hot. Refrigerate leftovers immediately or discard.



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SAFE HANDLING INSTRUCTIONS
THIS PRODUCT WAS PREPARED FROM INSPECTED AND PASSED MEAT AND/OR POULTRY. SOME FOOD PRODUCTS MAY CONTAIN BACTERIA THAT COULD CAUSE ILLNESS IF THE PRODUCT IS MISHANDLED OR COOKED IMPROPERLY. FOR YOUR PROTECTION, FOLLOW THESE SAFE HANDLING INSTRUCTIONS:
KEEP REFRIGERATED OR FROZEN TO MAINTAIN QUALITY.

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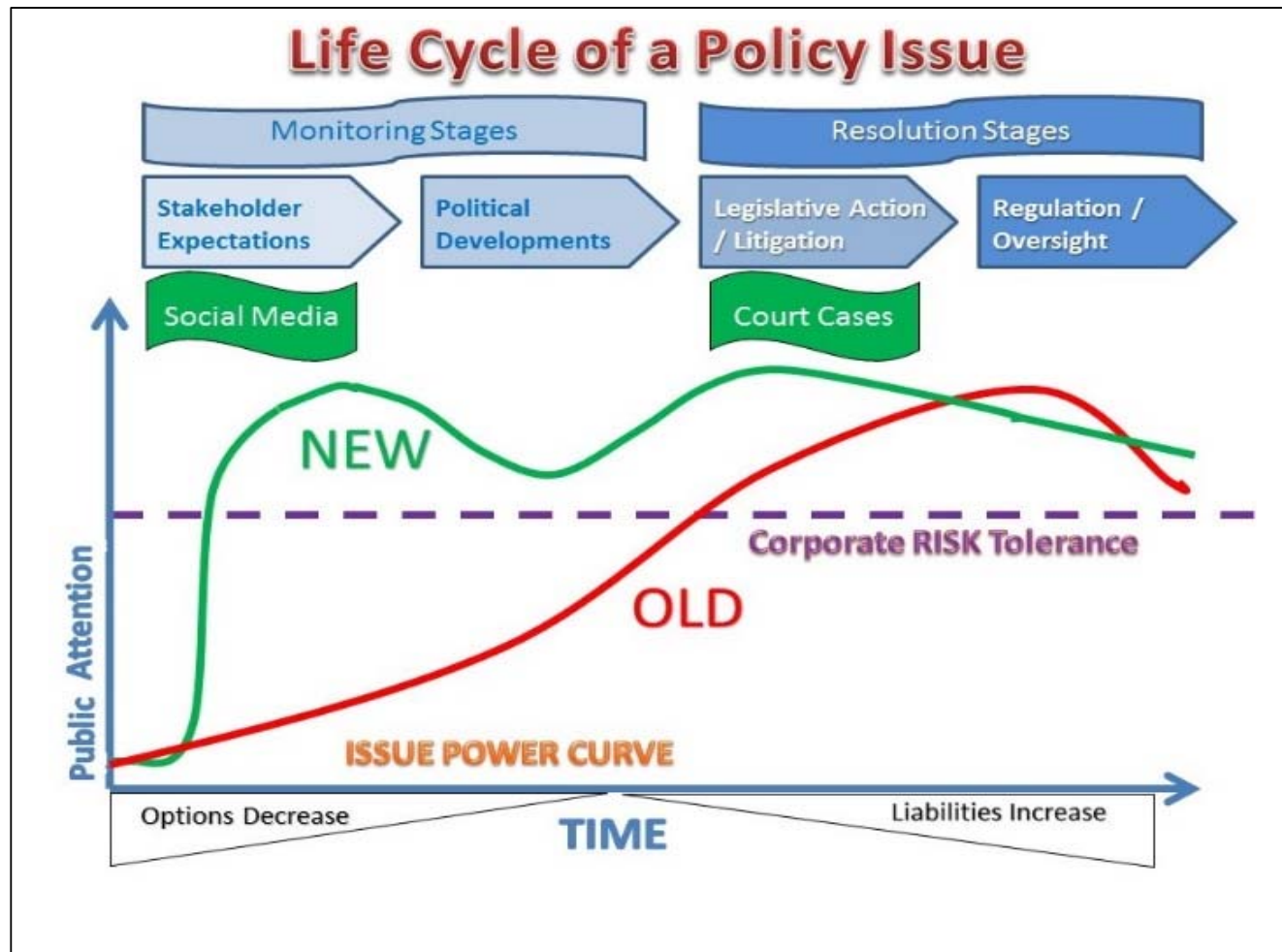
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Life Cycle of a Policy Issue. Graphic by Darin Detwiler, based on earlier graphs (Ashley & Morrison, 1996, Carroll & Buchholtz, 2012).

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