A Global View of the First Amendment Constraints on FDA

KRISTA HESSLER CARVER*

I. INTRODUCTION

Throughout its history, the Food and Drug Administration (FDA) has regulated two primary categories of subject matter: substances and words.[1] Several recent First Amendment cases raise doubt as to whether FDA has been performing its job correctly with respect to the latter.[2] Specifically, in *Washington Legal Foundation*, *Pearson*, and *Western States*, FDA suffered major First Amendment defeats with regard to several of its speech restrictions.[3] Before these cases, FDA had contended that the First Amendment did not apply to it, citing case law that suggested incidental restrictions on speech in highly regulated areas did not trigger First Amendment analysis.[4] These cases therefore sharply conflicted with previous FDA policy on First Amendment issues.[5]

For some time after *Washington Legal Foundation* and *Pearson*, FDA resisted change in its policies to accommodate these decisions.[6] After several years, the string of defeats and an administration change together prompted change at FDA. In August 2001, President Bush appointed Daniel Troy, a well-known lawyer who had argued in favor of a more expansive interpretation of the First Amendment, to the position of Chief Counsel of FDA.[7] Troy recognized that the pattern of

* Ms. Carver is an Associate in the law firm of Covington & Burling LLP, Washington, D.C. The views presented are those of the author and not those of Covington & Burling LLP or any of its clients. This article was written while the author was a law student in 2005-2006, attending Harvard Law School, Cambridge, Massachusetts, for Harvard Law School's Winter 2006 Food and Drug law course and in fulfillment of degree requirements and was updated by the author for inclusion in the journal. The writing of the paper was supervised by Lecturer on Law Peter Barton Hutt, Senior Counsel at Covington & Burling LLP, Washington, D.C. This paper won the Irving Oberman Memorial Prize for First Amendment Law at Harvard Law School.

[1] *See* Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, Food and Drug Law: Cases and Materials 5 (Foundation Press 2007); *see also* Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942, 34,943 (May 16, 2002) (noting much FDA regulation "depends on the use of words").

[2] *See* Gina Kolata, *Stung by Courts, FDA Rethinks Its Rules*, N.Y. TIMES, (Oct. 15, 2002), at F1.

[3] Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002); Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. (1999)); Washington Legal Found. v. Henney, 56 F. Supp. 2d 81 (D.D.C. (1999)); Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. (1998)); *see* Edward M. Basile & Melanie Gross, *The First Amendment & Federal Court Deference to the Food and Drug Administration: The Times They Are A-Changin'*, 59 FOOD & DRUG L.J. 31, 31, 38-42 (2004).

[4] Food Labeling; General Requirements for Health Claims for Food, 58 Fed. Reg. 2,478, 2,525 (Jan. 6, 1993) (citing S.E.C. v. Wall Street Pub. Inst. Inc., 851 F.2d 365, 372 (D.C. Cir. (1988)); Brief for Respondents at *21-24, Wellife Prods. v. Shalala, 52 F.3d 357 (D.C. Cir. (1995)) (No. 94-1293), 1995 WL 17204455 (quoting *Wall Street*, 851 F.2d at 373) ("[i]n such an area of extensive Federal regulation, the Government may place restrictions on speech that bears [sic] directly on the Government's objectives").

[5] *See, e.g.*, John Kamp, Daniel E. Troy & Elizabeth Alexander, *FDA Marketing v. First Amendment: Washington Legal Foundation Legal Challenges to Off-Label Policies May Force Unprecedented Changes at FDA*, 54 FOOD & DRUG L.J. 555, 555-57 (1999).

[6] Pearson v. Thompson, 141 F. Supp. 2d 105, 112 (D.D.C. 2001) ("Defendants again seem to ignore the thrust of Pearson I. … FDA has again refused to accept the reality and finality of [the Pearson I] conclusion. …").

[7] James G. Dickinson, *FDA's Law Chief is a Friend of Marketers; Food and Drug Administration's Daniel E. Troy*, MED. MKTG. & MEDIA, (Oct. 1, 2001), at 14.

unfavorable case law warranted action, and, in May 2002, FDA requested public comment "to ensure that [FDA's] regulations, guidances, policies, and practices … comply with the governing First Amendment case law."[8]

This article evaluates the First Amendment propriety of FDA's current regulatory regime under the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) and its accompanying regulations, Guidance documents and statements of policy. Section II identifies the features of the statute and implementing regulations that involve speech and therefore implicate the First Amendment. Section III describes governing Supreme Court First Amendment doctrine. Section IV discusses FDA-specific First Amendment case law. Section V analyzes the constitutional validity of FDA's policies based on the governing doctrine and the comments received in response to FDA's request and identifies policies that require revision. Section VI concludes that a fundamental shift has occurred in the way FDA does business as a direct result of the First Amendment case law.

II. FEATURES OF THE FDCA THAT IMPLICATE SPEECH

A. *Evidentiary Use of Speech to Determine Product Status*

A fundamental issue under the FDCA is whether a product is a "food," "drug," "device" or "cosmetic," because each is subject to different rules. A manufacturer's "representations in connection with [the product's] sale,"—in other words, its speech—are used to ascertain the product's intended use, which is then used as a trigger for classification into one or more of the statutorily defined product groups.[9] Specifically, FDA uses labeling, advertising, other promotional material, and, in limited instances, any other "relevant source" —including the circumstances under which the product is sold, packed or distributed—to ascertain intended use.[10] Thus, the use of words in describing products is crucial to their classification and the applicable regulatory rules.

B. *Labels and Labeling*

This section outlines the general and specific labeling requirements for different types of products.

1. *General Statutory and Regulatory Framework for Labels and Labeling*

"Label" and "labeling" are defined in the FDCA definitions section, and these definitions apply to the regulation of food, drugs, devices and cosmetics without

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[8] Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942, 34,942 (May 16, 2002).

[9] 21 U.S.C. § 321(g), (h), (i) (2000) (amended 2007); S. REP. NO. 74-361, at 4 (1935) ("The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put."). The statute refers to manufacturer intent as the basis for determining whether a product meets the definition of a "drug," "device" and "cosmetic." *See* 21 U.S.C. § 321(g)(1)(B) & (C), (i), (h). The definition of "food" does not explicitly reference intent. Because "drug" is defined as "articles (other than food)," manufacturer intent also affects whether a product is a "food." *Id.* § 321(g)(1)(C); *see also* JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 9:1 (2d ed. (2005)).

[10] 21 C.F.R. § 201.128 (2007); Nat'l Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 334 (2d Cir. (1977)).

differentiation.[11] A "label" includes written information attached to the product container, while "labeling" includes information on the article itself, on its containers or wrappers, and materials accompanying it.[12] In *Kordel*, the Supreme Court broadly interpreted "labeling" to be a "function[al]" term that reflected an "interdependent" relationship between the product and the literature, and held information need not physically accompany the product to constitute labeling.[13] FDA has interpreted "labeling" in its regulations even more broadly, including items that are:1) "descriptive of a drug; 2) supplied by the manufacturer or its agents; and 3) intended for use by medical personnel.[14]

The FDCA defines both misleading statements and failure to reveal material facts in a label or labeling as "misbranding."[15] FDA's regulations correspondingly include both affirmative disclosure obligations—labeling statements that must be included—and negative labeling prohibitions that specify content that *cannot* be included in labeling.

2. *Specific Labeling Requirements by Product Type*

This section describes the speech prohibitions and affirmative disclosure requirements for each category of FDA-regulated products. The label and labeling requirements and prohibitions for conventional food, dietary supplements, over-the-counter (OTC) drugs, prescription drugs, unapproved drugs, animal feed, animal drugs, devices and cosmetics are outlined.

a. Conventional Food

The FDCA imposes affirmative and negative food labeling rules. For example, a manufacturer cannot label its product with the name of another food.[16] If the product substitutes for and resembles a traditional food but is "nutritionally inferior," a food must bear the statement "imitation" in its statement of identity.[17] The statute mandates that the information on the label or in the labeling be sufficiently "prominent."[18]

The regulations impose several affirmative labeling requirements, including the following: 1) the statement of identity (either the standardized typical name for the food or a "fanciful" name used for consumers' benefit when the nature of the food is obvious); 2) the net contents statement; 3) a statement of the manufacturer's name and address (the responsibility statement); 4) a statement of the product's ingredients; and 5) nutrition labeling.[19] Additionally, the labeling information must be presented in a specified format, including type size and package panel location.[20]

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[11] 21 U.S.C. § 321; Hutt, Merrill & Grossman, *supra* note 1, at 98-99.

[12] 21 U.S.C. § 321(k) & (m).

[13] Kordel v. United States, 335 U.S. 345, 349 (1948).

[14] 21 C.F.R. § 202.1(l).

[15] 21 U.S.C. § 321(n).

[16] *Id.* §§ 321(n), 343(d); *see also* Daniel A. Kracov, *The Regulation of Foods and Food Additives*, *in* PRACTICAL GUIDE TO FOOD AND DRUG LAW 173 (Kenneth R. Pina & Wayne L. Pines eds., 2d ed. (2002)).

[17] FDA Center For Food Safety and Applied Nutrition (CFSAN), *A Food Labeling Guide*, Chapter 2 (1999), http://www.cfsan.fda.gov/~dms/flg-toc.html [hereinafter *Food Labeling Guide*]; FDA, *What are FDA Requirements for Imitation Foods?*, http://www.cfsan.fda.gov/~dms/qa-ind6d.html.

[18] 21 U.S.C. § 343(e).

[19] 21 C.F.R. § 101.3; Kracov, *supra* note 16, at 174-175.

[20] 21 C.F.R. §§ 101.1, 101.2(a), 101.3(a), 101.105(a); *see also Food Labeling Guide*, *supra* note 17, Chapter 1; Kracov, *supra* note 16, at 174.

The statement of identity regulations limit a manufacturer's labeling options. A food with a common or usual name *must* be labeled with this name, not a new name, and if it is subject to a standard of identity, must be labeled with that standardized name.[21] Similarly, the ingredient statement must include a listing of the product's ingredients, including flavors, preservatives and color additives in descending order of predominance by weight, utilizing their common names (except for those color additives where the certified names are used), unless a regulation provides for another name. [22] Labels must also clearly identify the source of all ingredients that are (or are derived from) the eight most common food allergens.[23] Currently, irradiated food must generally be labeled with a "radiation disclosure statement" and a particular logo reflecting that the product has been irradiated.[24] Under a proposed rule, however, FDA would limit this requirement to foods where the "irradiation causes a material change" in the food or the consequences of using the food.[25] It would also permit, in certain circumstances, the use of alternative terminology rather than "irradiated," such as "pasteurized."

Nutrition labeling requires the now-ubiquitous "Nutrition Facts" panel on food containers.[26] Five core pieces of information—calories, fat, sodium, carbohydrates and protein—must always appear on the label.[27] Generally, the following items are mandatory if the nutrients are present in the food: content of calories from fat, saturated fat, trans fat, cholesterol, potassium, dietary fiber, sugars, vitamins A and C, calcium and iron.[28] Additional information is voluntary unless a claim is made about the ingredient or the food is fortified or enriched with the ingredient, though only statutorily specified "voluntary" nutrients may be included in the Nutritional Facts box.[29] According to FDA, nutritional labeling for conventional food differs from that for dietary supplements in that manufacturers "may list the source of a dietary ingredient in the 'Supplement Facts' panel for dietary supplements" but "cannot list the source of a dietary ingredient in the 'Nutrition Facts' panel for foods."[30]

b. Dietary Supplements

Because dietary supplements are defined as "food" under the FDCA, the basic components of dietary supplement labeling, including the nutrition information and statements of identity, ingredients, responsibility and net quantity, are generally the same as those for conventional food.[31] Furthermore, the Supplement Facts

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[21] 21 C.F.R. § 101.3(b)(2); *Food Labeling Guide*, *supra* note 17, Chapter 2.

[22] 21 C.F.R. § 101.4(a); *Food Labeling Guide*, *supra* note 17, Chapter 4; Kracov, *supra* note 16, at 175.

[23] FDA, *Food Facts: Food Allergies: What You Need to Know*, http://www.cfsan.fda.gov/~dms/ff-alrgn.html.

[24] 21 C.F.R. § 179.26(c).

[25] Irradiation in the Production, Processing, and Handling of Food, 72 Fed. Reg. 16,291, 16,291 (proposed Apr. 4, 2007).

[26] *Food Labeling Guide*, *supra* note 17, Chapter 5. If this nutrition information is located elsewhere on the box besides in the Nutrition Facts panel, it is a nutrition claim, and the regulatory structure discussed below in the Claims section of this paper applies. 21 C.F.R. § 101.13(c).

[27] *Food Labeling Guide*, *supra* note 17, Chapter 5; Kracov, *supra* note 16, at 177-178.

[28] 21 C.F.R. § 101.9(c), (f); *see* Kracov, *supra* note 16, at 178.

[29] *Food Labeling Guide*, *supra* note 17, Chapter 5; Kracov, *supra* note 16, at 178.

[30] *See* FDA, Guidance for Industry, *A Dietary Supplement Labeling Guide*, Chapter 4 (2005), http://www.cfsan.fda.gov/~dms/dslg-toc.html [hereinafter *Dietary Supplement Labeling Guide*].

[31] 21 U.S.C. § 321(ff); Megan L. Foster & Daniel E. Dwyer, *The Regulation of Dietary Supplements*, *in* PRACTICAL GUIDE TO FOOD AND DRUG LAW, *supra* note 16, at 222.

box required by the governing law is similar to the Nutrition Facts box, but has its own precise formatting and content requirements.[32]

The main difference between dietary supplement and food regulation lies in the nutrition labeling.[33] The source of an ingredient and part of the plant from which it is derived must be included on supplement labeling but are prohibited on food labeling.[34] Zero amounts are not permitted on supplement labeling but are required on food labeling.[35]

The "'third party literature' exemption" excludes certain literature about dietary supplements from regulation as labeling.[36] This exemption allows manufacturers to distribute scientific journal articles, textbooks and other materials to promote the sale of dietary supplements if the materials: 1) are truthful and nonmisleading; 2) do not promote a certain brand or manufacturer; 3) do not have any additional stickers or other information affixed to them; 4) present a "balanced view" of the information; and 5) are "physically separate" from the dietary supplements in any store displays.[37]

c. OTC Drugs

Like other products, OTC drug labeling and packaging—including the "Drug Facts" box—cannot contain false or misleading statements.[38] "Misleading statements" include the use of a drug name that suggests the product is another drug or that it has only one of its many active ingredients.[39] A drug also must meet numerous affirmative disclosure requirements. The labeling must include 1) a responsibility statement; 2) a net contents statement; 3) a statement of identity that is the drug's established name, the active ingredients, and the inactive ingredients; 4) a statement describing the drug's pharmacological category and intended uses, located next to the drug's proprietary name; 5) "adequate directions for use;" 6) "adequate warnings;" and 7) an expiration date (unless has no dosage limits and is "stable" for three or more years).[40]

To meet the adequate directions requirement, the indications for use must be included with the directions, which must be printed on the outside and inside of the package.[41] OTC drug directions may fail to include "adequate directions" for a number of reasons, such as errors or omissions in: 1) description about intended use; 2) dosage information; 3) information about frequency, route, time and duration of administration; and 4) preparation instructions.[42]

The regulations also direct manufacturers as to how they may organize the information on the package, and how they may name their products and ingredients. Ingredient labeling may be misleading through usage of "fanciful" names for the drug or ingredient, improper order of ingredients, listing of "filler" ingredients so as to create the perception of greater value, and use of a confusing proprietary name

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[32] Foster & Dwyer, *supra* note 31, at 223.

[33] *Dietary Supplement Labeling Guide*, *supra* note 30, Chapter 4.

[34] *Id.*

[35] *Id.*

[36] 21 U.S.C. § 343-2(a).

[37] *Id.*; *see also* Foster & Dwyer, *supra* note 31, at 222.

[38] 21 U.S.C. § 352(a), (g), (i).

[39] 21 C.F.R. § 201.6.

[40] 21 U.S.C. § 352(b), (c), (e), (f); 21 C.F.R. § 201.61(b), (c); CTFA LABELING MANUAL: A GUIDE TO LABELING AND ADVERTISING COSMETICS AND OTC DRUGS 80-81 (Thomas J. Donegan, Jr. & Catherine C. Beckley eds., 6th ed. (1997)).

[41] 21 C.F.R. § 201.61(b); CTFA LABELING MANUAL, *supra* note 40, at 80.

[42] 21 C.F.R. § 201.5(a)-(g).

for an ingredient.[43] The labeling information must be formatted as directed in the regulations, including with regard to label location, type size, titles, etc.[44]

A manufacturer's discretion is highly constrained in the area of OTC drug warning language. Some OTC drugs must contain specific poison-control warnings, and it is recommended that all do so.[45] All drugs must also bear the warnings required by their official compendia.[46] The regulations provide required and recommended warning statements for specific drug components.[47] The required warning statements specify the exact language to be used.[48]

Additional labeling requirements may be imposed by the particular governing OTC drug monograph for any given drug.[49] To market the drug without applying for a new drug application (NDA), the manufacturer must comply with these requirements.[50] For some time FDA utilized an "exclusivity" policy, under which OTC drug labeling pursuant to a monograph was required to have the *exact* language specified in the monograph, or else the drug would be misbranded.[51] In a subsequent rulemaking, FDA amended this policy as to indications for use, allowing one of three language choices: the exact monograph language (as before), "alternative" language conveying the same ideas and excluding false or misleading information, or a combination of the two.[52] The statement of identity and most other labeling must be in the *exact* language specified by the OTC monograph, except where the regulations specify synonyms may be used.[53]

The rules are different for OTC drugs with tentative final monographs. Once a tentative final monograph has been published and remains unchanged in the wake of initial comments, the agency may allow marketing to begin under preliminary labeling (though the manufacturer will assume the risk that the agency will change its tack and require corrective action).[54] Moreover, the FDA Compliance Policy Guide provides that the agency will only pursue enforcement action for labeling deficiencies on these drugs if the deficiencies constitute a "potential hazard to health."[55]

d. Prescription Drugs

The regulatory labeling framework for prescription drugs is generally similar to that of OTC drugs. Prescription drugs must comply with the provisions that deem a drug misbranded if the labeling is "false or misleading in any particular," the drug is listed in an official compendium but is not packaged and labeled as prescribed therein, the container is misleading, or the packaging or labeling violates the corresponding regulations.[56] Many other labeling regulations for prescription drugs

[43] *Id.* § 201.10(c).

[44] *Id.* §§ 201.15, 201.66.

[45] *Id.* §§ 330.1, 369.9.

[46] *Id.* § 369.7.

[47] *Id.* §§ 369.20, 369.21.

[48] *See* George W. Evans & Arnold I. Friede, *The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis*, 58 FOOD & DRUG L.J. 365, 381-383, 398 (2003).

[49] CTFA LABELING MANUAL, *supra* note 40, at 82.

[50] *Id.*

[51] Labeling of Drug Products for OTC Human Drug Use, 51 Fed. Reg. 16,258, 16,258-59 (May 1, 1986).

[52] *Id.*; *see also* 21 C.F.R. § 330.1(c)(2).

[53] 21 C.F.R. § 330.1.

[54] *Id.* § 330.14(h).

[55] Food and Drug Administration, COMPLIANCE POLICY GUIDE 7132b.15 § 450.200 (1995), *available at* http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg450-200.html.

[56] 21 U.S.C. § 352(a), (g), (h), (i)(1) & (i)(2), (p).

are identical as those for OTC drugs, including the adequate directions regulation and false/misleading labeling regulation.[57]

The labeling content and format requirements were recently amended. The new rule requires inclusion of a "highlights" section and a table of contents, in addition to product name, indications and usage, dosage and administration, dosage forms and strengths, contraindications, warnings and precautions, adverse reactions, drug interactions, uses in specific populations, drug abuse and dependence, overdosage, description, clinical pharmacology, nonclinical toxicology, clinical studies, reference, storage and handling, and patient counseling information.[58] FDA may require particularly serious health risks to be placed in a "black box" on the package insert to make them more obvious.[59]

FDA specifically prescribes the language of prescription warning statements when it approves the physician package insert.[60] Regulations also specify required warnings for many individual prescriptions.[61] Manufacturers may not express any "differences of opinion" as to required warnings or efficacy (unless supported by substantial evidence in the latter case).[62] Furthermore, changes in the labeling generally may not be made without prior FDA approval.[63] Changes that are minor may be made without FDA approval, and changes to "add or strengthen" warnings and certain other changes in labeling may be made contemporaneously with the filing of a supplement to FDA and subject to a subsequent approval requirement.[64]

e. Animal Feed/Drugs

The statutory definitions of "food" and "drug" include human *and* animal food and drugs.[65] Thus, the previously described regulatory speech requirements for human food and drugs are applicable generally to animal feed and drugs also.[66]

Like human food, animal feed is required to bear labeling that includes the same information, in the same order, concerning: 1) proper product name; 2) net quantity statement; 3) responsibility statement; and 4) ingredients listing.[67] The

[57] 21 C.F.R. §§ 201.2, 201.5, 201.6, 201.15, 201.25.

[58] 21 C.F.R. § 201.56(d)(1), (e); Requirements on Format and Content of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,922 (Jan. 24, 2006).

[59] 21 C.F.R. § 201.57(e); Judith E. Beach et al., *Black Box Warnings in Prescription Drug Labeling: Results of a Survey of 206 Drugs*, 53 FOOD & DRUG L.J. 403, 403 (1998). Beach and her co-authors conclude that "FDA reserves black box warnings generally for those situations in which 1) there is a strong clinical database to define the risk or hazard, and 2) the medical practitioner's attentiveness to the highlighted risk has important clinical significance that requires the judgment of that practitioner." Beach, *supra*, at 410.

[60] Hutt, Merrill & Grossman, *supra* note 1, at 483-484, 493-507, 725.

[61] *See* 21 C.F.R. §§ 201.301-201.323.

[62] *Id.* § 1.21(c).

[63] *Id.* § 314.70.

[64] *Id.* § 314.70(c) & (d). Changes to the Highlights may only be made with prior FDA approval, *id.* § 314.70(b)(2)(v)(C), which narrows the scope of labeling changes that may be made using a "changes being effected" supplement. Additionally, because FDA could disapprove these changes being effected supplements after submission, in practice companies wait for FDA to review and approve them before implementing the changes, and FDA expects this practice. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,934 (Jan. 24, 2006).

[65] 21 U.S.C. § 321(f), (g) (defining "food" as "articles used for food or drink for man *or other animals*" and also defining "drug" with regard to "other animals" as well as man) (emphasis added); Hutt, Merrill & Grossman, *supra* note 1, at 835.

[66] Hutt, Merrill & Grossman, *supra* note 1, at 835.

[67] 21 C.F.R. §§ 501.3, 501.4, 501.5; 501.105(a); David A. Dzanis, *Interpreting Pet Food Labels: Part I: General Rules*, FDA VETERINARIAN, (Nov.-Dec. 1998), at 2-5, *available at* http://www.michigan.gov/documents/Interpreting_Pet_Food_Labels_-_Part_1_(DD)_125168_7.pdf.

proper product name is dependent on the percentage composition of the animal feed.[68] Likewise, the regulations provide for a statement of identity created with the same guidelines as for food.[69] Several specific warnings are dictated for certain animal foods, such as those in pressurized containers.[70] In summary, the guidelines for animal feed labeling are similar to those for human food.

The main provision for labeling of animal drugs operates to prohibit disclaimers of liability that contend the drug is not safe and effective.[71] Only products with an approved new animal drug application can be labeled with nutrition and health claims.[72] Finally, off-label use of animal drugs is permitted if prescribed by a veterinarian and meeting promulgated regulations.[73]

f. Devices

The device labeling requirements consist of prohibitions and affirmative disclosures. The major prohibition is against false and misleading statements, including failure to disclose material facts.[74] The affirmative labeling requirements for devices have four main parts: 1) a responsibility statement; 2) adequate directions for use; 3) the statement of identity (including the common name of the product and explaining its intended use); and 4) "adequate warnings" concerning "use in those pathological conditions or by children where its use may be dangerous to health" and unsafe dosage, methods of administration/application or duration of use.[75] FDA has promulgated regulations mandating warnings for some particular devices.[76]

Formatting requirements, such as legibility, placement and spacing requirements, also apply.[77] The manufacturer is obligated to provide adequate labeling for known off-label uses.[78] Furthermore, current FDA policy requires certain changes in the labeling be subjected to a premarket approval application (PMA) supplement or new 510(k) as applicable.[79]

g. Cosmetics

Under the FDCA, cosmetics are subject to general prohibitions against adulteration and misbranding.[80] Misbranding occurs if 1) the labeling or container is false or misleading; 2) the package does not bear a responsibility statement; 3) the required label information is not legible; 4) the packaging or labeling does not comply with color additive requirements; or 5) the packaging violates the Fair Packaging and Labeling Act (FPLA).[81] The prohibition on misleading labeling extends to the

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[68] 21 C.F.R. § 501.3(f).

[69] *See id.* §§ 501.1-501.15.

[70] *Id.* § 501.17.

[71] *Id.* § 500.51.

[72] Inapplicability of the Dietary Supplement Health and Education Act to Animal Products, 61 Fed. Reg. 17,706, 17,706 (Apr. 22, 1996).

[73] 21 U.S.C § 360b(a)(4); *see also* Linda Bren, *Treating Minor Species: A Major Animal Health Concern*, FDA VETERINARIAN, (Sept.-Oct. 2002), at 11, *available at* http://www.fda.gov/cvm/Documents/SeptOct.pdf.

[74] 21 U.S.C. § 352(a), (n); *see also* FDA, *Device Advice: Labeling Requirements-General*, http://www.fda.gov/cdrh/devadvice/331.html [hereinafter *Device Advice*].

[75] 21 U.S.C. § 352(f); 21 C.F.R. §§ 801.1, 801.5, 801.61; *see also* Edward M. Basile, Ellen Armentrout & Kelly N. Reeves, *Medical Device Labeling & Advertising: An Overview*, 54 FOOD & DRUG L.J. 519, 521-523 (1999); *Device Advice*, *supra* note 74.

[76] *See, e.g.,* 21 C.F.R. §§ 801.433, 801.63.

[77] *Id.* § 801.15 (a); *see also* Basile et al., *supra* note 75, at 522.

[78] 21 C.F.R. § 801.4.

[79] *Id.* § 814.39.

[80] 21 U.S.C. §§ 361-362.

[81] *Id.* § 362.

names of the cosmetic product and this prevents a product name that includes or suggests one or more but not all of its ingredients.[82]

Cosmetics labeling must include an ingredients statement on the outer package, using the ingredients' compendia names, and a statement of identity.[83] Warning statements are required when "necessary or appropriate to prevent a health hazard that may be associated with the product."[84] FDA may establish required warnings for certain cosmetics, including for all products in a related class, if it has "adequate factual basis."[85] Formatting and prominence requirements also apply for the labeling content.[86]

Finally, the key portion of the affirmative labeling requirements ties in with safety testing. Cosmetics ingredients and products must be "adequately substantiated for safety" before being sold, or, if insufficient testing has been conducted, they must bear a label indicating that their safety has not been determined.[87] Moreover, the required use of this warning cannot be definitively avoided. FDA may, at any time, reinstate the warning upon development of new information and could "retroactively find failure to warn" at that time based on inadequate testing.[88]

C. *Claims*

1. *Food Claims*

a. Health Claims

Health claims are statements that directly or indirectly characterize the relationship of nutrients in food to a disease or health-related condition.[89] Generally, a health claim for a conventional food is permitted only when FDA has promulgated a regulation specifying its precise language and the conditions under which it may be used.[90] Claims made in compliance with the governing regulations do not render the food a drug, but foods containing other claims are not eligible for this safe harbor and may be considered "drugs."[91]

Manufacturers may petition for a health claim, and FDA must rule on a requested claim within 540 days.[92] To permit the claim, FDA must determine, on the basis of all available scientific evidence, that there is "significant scientific agreement" that the evidence supports the claim.[93] Despite the existence of such evidence, some claims will be nonetheless barred because the food contains a "disqualifying" level

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[82] 21 C.F.R. §§ 701.2(b)(1)), 701.3; *see also* CTFA LABELING MANUAL, *supra* note 40, at 69.

[83] 21 C.F.R. § 701.11.

[84] *Id.* § 740.1.

[85] *Id.*; O'REILLY, *supra* note 9, § 17:6.

[86] 21 C.F.R. §§ 701.10, 701.2, 740.2.

[87] *Id.* § 740.10. O'REILLY, *supra* note 9, § 17:6.

[88] 21 C.F.R. § 740.10(b). Some safe harbors are available. *Id.*

[89] 21 C.F.R. § 101.14(a)(1); Kracov, *supra* note 16, at 181.

[90] 21 U.S.C. § 343(r)(2)(A)(i); Kracov, *supra* note 16, at 181.

[91] 21 U.S.C. § 321(g)(1).

[92] 21 C.F.R. §§ 101.69(m)(5), 101.70(j)(4)(ii).

[93] 21 U.S.C. § 343(r)(3)(B)(i). In Guidance, FDA defines "significant scientific agreement" to mean that "the validity of the relationship is not likely to be reversed by new and evolving science." FDA, Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Food and Dietary Supplements, Introductory Note (Dec. 22, 1999), http://www.cfsan.fda.gov/~dms/ssaguide.html; *see also* Draft Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims § II (July 9, 2007), http://www.cfsan.fda.gov/~dms/hclmgui5.html (intended to replace the 1999 Guidance). According to the Draft Guidance, the assessment of significant scientific agreement "derives from the conclusion that there is a sufficient body of relevant scientific evidence that shows consistency across different studies and among different researchers." Draft Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims § II (July 9, 2007), http://www.cfsan.fda.gov/~dms/hclmgui5.html.

of a substance, like fat or cholesterol, which augments the risk of a disease or a diet-related health condition in people "in the general population."[94]

Guidance allows for qualified health claims (claims which do not meet the "significant scientific agreement" standard but are "qualified" in some way to make them truthful and nonmisleading), in accordance with the First Amendment right of free speech,[95] but requires pre-approval via petition.[96] The petition must describe how the claim is supported by "credible evidence," explain how it is accurate and nonmisleading and analyze the effects of the claim on individuals, preferably using consumer research.[97] A disclaimer is required depending on the level of scientific evidence supporting the claim.[98] FDA continues to evaluate *unqualified* health claims under the "significant scientific agreement" standard.[99] FDA will only permit health claims that are aimed at risk reduction, and considers claims about disease mitigation or treatment to be drug claims not authorized for use in foods.[100]

b. Nutrient Content Claims

Nutrient content claims, also known as descriptors, are claims that directly or implicitly characterize the quantity of a nutrient in a food.[101] Generally, nutrient content claims may not be made except in accordance with applicable FDA regulations and must recite the exact language provided by FDA.[102] The only exception is that claims made in compliance with the authoritative statement rule, explained below, are permitted.[103] FDA must rule on a requested claim within 540 days.[104]

Two forms of descriptors are allowed: absolute and relative or comparative.[105] Absolute claims specify the level of a nutrient in a product, whereas relative claims compare the amount of the nutrient in the product with that amount in a similar product.[106] Absolute claims must use the specific descriptive terms approved by FDA and may not deviate from these terms.[107] Relative claims are allowed only when the food is compared to an "appropriate reference food," which is narrowly defined, and the label must bear the relevant nutritional information for the reference food.[108] A manufacturer may petition FDA to promulgate definitions for new nutrient content claims, accept synonym usage for terms in current claims, or allow the use of implied descriptors in product names.[109] Overall, however, FDA's

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[94] 21 U.S.C. § 343(r)(2)(A)(iii); 21 C.F.R. § 101.14(a)(4). The statute does, however, allow FDA to permit this type of claim "based on a finding that such a claim would assist consumers in maintaining healthy dietary practices," accompanied by appropriate disclaimers. 21 U.S.C. § 343(r)(3)(A)(ii).

[95] Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. (1999)).

[96] Guidance for Industry: FDA's Implementation of Qualified Health Claims: Questions and Answers (May 2006), http://www.cfsan.fda.gov/~dms/qhcqagui.html.

[97] FDA, Guidance for Industry and FDA, Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements § III(C)(2) (July 10, 2003), http://www.cfsan.fda.gov/~dms/hclmgui3.html [hereinafter Qualified Claims Interim Procedures].

[98] *Id.*

[99] *Id.*

[100] *See* Whitaker v. Thompson, 353 F.3d 947, 948-949 (D.C. Cir. (2004)).

[101] *Food Labeling Guide*, *supra* note 17, Chapter 6.

[102] *Id.*; *see also* 21 C.F.R. § 101.13(b).

[103] 21 C.F.R. § 101.13(b); *Food Labeling Guide*, *supra* note 17, Chapter 6.

[104] 21 C.F.R. §§ 101.69(m)(5), 101.70(j)(4)(ii).

[105] Comments of Grocery Mfrs. of Am. in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C21, at 13 (Sept. 10, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091002/80025d51.pdf; Kracov, *supra* note 16, at 180.

[106] Kracov, *supra* note 16, at 180.

[107] *Food Labeling Guide*, *supra* note 17, Chapter 6.

[108] 21 C.F.R. § 101.13(j).

[109] *See id.* § 101.13(b); *Food Labeling Guide*, *supra* note 17, Chapter 6; Kracov, *supra* note 16, at 180.

failure to define a category of nutrients for descriptors will operate as a *de facto* ban on reference to such nutrient.[110] Furthermore, some nutrient content claims are prohibited if the amount of another component (like cholesterol) exceeds a certain level.[111]

The use of a nutrient content claim may trigger additional disclosure requirements to ensure that the label is nonmisleading.[112] Disclosure statements—a warning that the amount of a component is so high that it may be harmful—are required where a nutrient content claim is made and the food contains fat, sodium, cholesterol or saturated fat above a specified amount. [113]

c. Structure-Function Claims

Structure-function claims relate a food or ingredient to an effect on the structure or function of the human body.[114] The food must be generally recognized as safe and the claim may not be misleading.[115] The sponsor is not required to notify FDA or provide disclaimers for the use of these claims.[116]

d. Authoritative Statement Claims

A sponsor may make a health or nutrient content claim without prior approval under this provision added in 1997. The claim with an "authoritative statement" is eligible if: 1) a governmental scientific body published the authoritative statement establishing the nutrient level or relationship between nutrients and health and it is still in effect; 2) the sponsor notifies FDA 120 days before actually using the claim, including the claim language, the authoritative statement and relevant, balanced scientific literature in this notification; 3) the claims are not made about certain foods that FDA has determined increase the risk of disease; and 4) the claims accurately represent the authoritative statement.[117]

2. Dietary Supplement Claims

a. Health Claims

As with conventional food, dietary supplement health claims are not permitted unless FDA has promulgated a regulation authorizing such claims and providing their explicit language, or the claims are "qualified" under FDA's standards.[118] Use of the regulation-authorized claims will not cause the dietary supplement to be considered a drug, but other claims could subject the product to regulation as

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[110] Comments of Grocery Manufacturers of America, Comment C21, *supra* note 105, at 13.

[111] *E.g.* 21 C.F.R. § 101.62; Comments of Nat'l Ass'n of Margarine Mfrs. in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C45, at 2, 4-5 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d31.pdf.

[112] *Food Labeling Guide*, *supra* note 17, Chapter 6.

[113] 21 C.F.R. § 101.13(h)(1)-(3).

[114] FDA CFSAN, Structure/Function Claims, http://www.cfsan.fda.gov/~dms/labstruc.html; Kracov, *supra* note 16, at 181.

[115] FDA CFSAN, Discussion of a Conceptual Framework for Structure and Function Claims for Conventional Foods (2000), http://www.cfsan.fda.gov/~dms/labstru2.html.

[116] FDA CFSAN, Structure/Function Claims, http://www.cfsan.fda.gov/~dms/labstruc.html. Because "drug" is defined with regard to structure-function claims as "articles (other than food) intended to affect the structure or any function of the body of man or other animals," structure-function claims do not turn a "food" into a "drug." 21 U.S.C. § 321(g)(1)(C).

[117] 21 U.S.C. § 343(r)(2)(G); Kracov, *supra* note 16, at 182.

[118] 21 C.F.R. § 101.14(e); *Dietary Supplement Labeling Guide*, *supra* note 30, Chapter 6; Foster & Dwyer, *supra* note 31, at 226.

a drug.[119] As with food, FDA may grant a petition for such claim if "significant scientific agreement" exists.[120] FDA also allows qualified claims, in which a health claim not meeting the "significant scientific agreement" standard may be used if it is followed by certain disclaimers.[121] Qualified claims are evaluated under the Guidance documents described in the conventional foods section.

b. Nutrient Content Claims

In most respects, the nutrient content regulatory regime is the same for dietary supplements as for conventional food.[122] The main distinction is that dietary supplement labeling may include claims about ingredients for which there is no statutory definition or recommended daily allowance.[123]

c. Structure-Function Claims

The FDCA allows four types of dietary supplement structure-function claims without prior FDA approval.[124] Specifically, claims may: 1) declare that the product is beneficial as to a "classical nutrient-deficiency disease" if the claim also "discloses the prevalence of such disease" in the nation; 2) describe how the nutrient affects the structure or function of the human body; 3) explain the mechanism by which the nutrient accomplishes this change in structure or function; and 4) describe general well-being derived from consumption of the nutrient.[125] These claims are permitted if the label bears the disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[126] The sponsor must have "substantiation" that the statement is not false or misleading for making the claim, and must notify FDA within thirty days of making such claim.[127] The disclaimer requirements are particular to dietary supplements and do not apply to conventional food.[128] Again, claims made in compliance with the governing regulations do not render the dietary supplement a drug, but dietary supplements containing other claims are not eligible for this safe harbor and will be considered "drugs."[129]

d. Disease Claims

Except for disease prevention claims specifically authorized by FDA, "disease claims" are prohibited for dietary supplements.[130] Dietary supplements making such claims will be regulated as drugs.[131] "Disease" for these purposes means damage to

[119] 21 U.S.C. § 321(g)(1).

[120] 21 C.F.R. §§ 101.14; *Dietary Supplement Labeling Guide*, *supra* note 30, Chapter 6.

[121] Guidance for Industry: FDA's Implementation of Qualified Health Claims: Questions and Answers, Question 2 (May 2006), http://www.cfsan.fda.gov/~dms/qhcqagui.html.

[122] 21 C.F.R. § 101.13.

[123] 21 U.S.C. § 343(r)(6).

[124] *Id.*; *see also* Foster & Dwyer, *supra* note 31, at 224.

[125] 21 U.S.C. § 343(r)(6); *see also* Foster & Dwyer, *supra* note 31, at 224.

[126] 21 U.S.C. § 343(r)(6).

[127] *See id.*, Comments of Consumer Healthcare Prods. Ass'n in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C67, at 6 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091802/80027f46.pdf; *see also* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1,000, 1,021-22 (Jan. 6, 2000).

[128] 21 C.F.R. § 101.93(b) & (c); *see also* Comments of Council for Responsible Nutrition in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C95, at 4 (Oct. 28, 2002), http://www.fda.gov/ohrms/dockets/dockets/02n0209/02n-0209-c000095-vol19.pdf.

[129] 21 U.S.C. § 321(g)(1).

[130] 21 C.F.R. § 101.93(f).

[131] *Id.*

a part of the body causing improper function, or a state of health leading to such dysfunction, excluding conditions from nutrient deficiencies.[132] FDA uses ten criteria to determine if a claim is a "disease claim."[133] Disease claims include language that makes an explicit or implicit claim that the product or an ingredient thereof has an effect on a specific disease, abnormality, or symptoms thereof; belongs to a class of products intended to diagnose, mitigate, treat, cure or prevent disease; substitutes for or augments a therapeutic disease therapy or allays the adverse effects thereof; or otherwise intimates an effect on either "disease" generally or a specific condition.[134] Claims may be inferred from the product name, statements about product formulation, references to literature in which a disease claim is made, graphic representations and uses of the term "disease" outside the scope of general disease prevention.[135] This broad interpretation of "disease" essentially means that dietary supplement claims "may not mention disease states even in the context of prevention or health maintenance."[136]

3. *Drugs*

By definition, drugs may contain both disease and structure-function claims.[137] FDA essentially controls the content of prescription and OTC drug claims through the NDA approval process and the OTC Drug Review, respectively.[138] Health claim limitations are, by definition, applicable only to foods and dietary supplements, not drugs.[139]

D. *Advertising*

"Advertising" is not defined anywhere in the FDCA, but is generally understood to include general media-based information in television, radio, magazines and professional journals.[140] FDA has jurisdiction over advertising for prescription drugs and restricted devices, while the Federal Trade Commission (FTC) has primary authority for advertising of other products that FDA otherwise regulates.[141]

1. *Prescription Drug Advertising*

As with other categories of product regulation, false and misleading statements in prescription drug advertisements are prohibited.[142] The regulations outline sixteen types of claims that FDA considers definitively "misleading," including unproven comparative claims and claims that the drug is safer than the evidence suggests

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[132] *Id.* § 101.93(g)(1).

[133] *Id.* § 101.93(g)(2).

[134] *See id.*; Foster & Dwyer, *supra* note 31, at 226.

[135] 21 C.F.R. § 101.93(g)(2)(iv).

[136] Comments of Nat'l Nutritional Foods Ass'n in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C28, at 2 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091302/80027ac3.pdf.

[137] *See* 21 U.S.C. § 321(g).

[138] *See* Hutt, Merrill & Grossman, *supra* note 1, at 477; *see also* 21 U.S.C. § 355(d).

[139] *See* 21 C.F.R. § 101.14. Health claims characterize the relationship of a food or dietary supplement to a disease or health-related condition. *Id.*

[140] Basile, *supra* note 75, at 520.

[141] 15 U.S.C. § 52; 21 U.S.C. § 352(n), (q), (r); CTFA LABELING MANUAL, *supra* note 40, at 123; Hutt, Merrill & Grossman, *supra* note 1, at 98; O'Reilly, *supra* note 9, § 18:10.

[142] 21 C.F.R. § 202.1(e)(6); *see also* 21 U.S.C. § 352(n).

through the use of "selective presentation" of scientific evidence.[143] It also describes thirteen types of claims FDA "may" find misleading, including those with inappropriate emphasis or prominence, those based on inadequate studies, and those not supported by statistical principles.[144] Other prohibitions apply as well. For example, advertisements may not use "fanciful" names for the product or suggest that inert ingredients have a beneficial effect when they do not.[145]

The advertising regulations have three main affirmative disclosure features. Advertisements must: 1) present a "fair balance" about the risk-benefit profile of the drug, which means they must mention all indicated negative information from the drug's labeling (i.e., side effects, warnings, precautions and contraindications, with equal prominence as the benefits); 2) contain facts material to the product's advertised uses; and 3) include a "brief summary" of the product's labeling that includes all risks.[146] Thus, advertisements must be consistent with the product labeling generally and the claims must be supported by substantial evidence.[147] Advertisements must include true statements of the established name, ingredients and drug formula.[148] Furthermore, the advertisement *must* refer to the drug's generic name in a specific size and place.[149]

Most prescription advertisements do not require prior approval of FDA before publication/broadcast.[150] Prior approval is, however, required when unpublished or minimally- circulated published reports surface that demonstrate the drug has caused serious side effects or death and the manufacturer refuses to "assur[e] that such information will be publicized promptly and adequately to the medical profession in subsequent advertisements."[151] Many advertisements must be filed with FDA "at or before the time of initial dissemination or publication," though.[152]

Manufacturers must comply with additional requirements for "Direct-to-Consumer" (DTC) advertising, which includes print and broadcast advertisements, videos, pamphlets, etc., that are paid for by a drug company, mention a specific product, and are expected to be viewed by consumers.[153] All non-broadcast DTC ads must comply with the statutory and regulatory requirements for general prescription drug advertising like the "brief summary" and "fair balance" requirements, and will need to include a conspicuous statement encouraging consumers to report

[143] 21 C.F.R. § 202.1(e)(6). FDA has enforced its requirement that comparative claims be supported by substantial evidence recently and vigorously, through Untitled and Warning Letters. *See, e.g.*, Letter from Michelle Safarik, Regulatory Review Officer, Division of Drug Marketing, Advertising, and Communications (DDMAC), to Munir Abdullah, Director, U.S. Regulatory Affairs, GlaxoSmithKline concerning Flonase (May 7, 2007), at 2; Letter from Suzanne Berkman, Regulatory Review Officer, DDMAC, to Scarlett Tumulty, Associate Director, KV Pharmaceuticals concerning Clindesse (May 17, 2007), at 5; Warning Letter from Thomas Abrams, Director, DDMAC, to Jeffrey Buchalter, CEO, Enzon Pharmaceuticals, Inc. concerning Abelcet (May 21, 2007), at 3-4; Warning Letter from Thomas Abrams, Director, DDMAC, to Alex Gorsky, CEO, Novartis Pharmaceuticals Corp. concerning Exelon® (Aug. 8, 2007), at 2-3; Letter from Robert Dean, Regulatory Review Officer, DDMAC, to Robert B. Clark, Vice President, Pfizer, Inc. concerning Geodon (July 16, 2007), at 2; *see also* Arnold I. Friede, *Recent Warning Letters for Ads Reflect FDA's Fixation on "Substantial Evidence,"* WASHINGTON LEGAL FOUNDATION LEGAL BACKGROUNDER, Aug. 10, 2007, at 1-3.

[144] 21 C.F.R. § 202.1(e)(7).

[145] *Id.* §§ 202.1(a)(3), (4), 314.640.

[146] *See generally id.* § 202.1

[147] *Id.*

[148] 21 U.S.C. § 352(n).

[149] 21 C.F.R. § 202.1.

[150] *See id.* § 202.1(f)(1).

[151] *Id.*

[152] *Id.* § 314.81(b)(3)(i).

[153] *See id.* § 202.1(e)(1).

negative side effects to FDA using a toll free number or the web-based Medwatch program.[154] Under Draft Guidance, the manufacturer can fulfill the "brief summary" requirement in DTC ads using any of the following methods: 1) reproducing FDA-approved patient labeling, either verbatim or modified to include only the major risk information such as warnings contraindications, precautions and some adverse reactions; 2) providing risk information appropriate for the "Highlights" portion of professional labeling, preferably in simple language; or 3) reproducing the approved physician labeling. [155]

FDA requests that DTC advertisements generally be filed with FDA before they are published or broadcast.[156] For drugs utilizing the accelerated approval process, sponsors must submit copies of all promotional materials that will be disseminated within a 120-day period following approval, and after this initial timeframe, must submit such materials 30 days before dissemination.[157] Under the recently enacted Food and Drug Administration Amendments Act of 2007 (FDAAA), FDA can require submission of drug advertisements 45 days or more before dissemination, and make recommendations for advertising changes that are necessary to protect consumers, ensure consistency with the prescribing information and address the drug's effects in specific subgroups.[158] FDA cannot make or direct the changes. Additionally, FDA can require, in pre-reviewed prescription drug advertisements, a "specific disclosure about a specific risk" in the drug's labeling and/or the drug's approval date within the first two years of approval, if FDA deems these disclosures necessary to prevent the advertisement from being false and misleading.[159]

For broadcast advertising, the brief summary requirement can be fulfilled using the "major statement," which summarizes the main side effects and contraindications of the drug in the audio/visual component of the broadcast.[160] In DTC advertisements that include the name of the drug and its conditions of use, the major statement relating to side effects and contraindications will need to be presented in a "clear, conspicuous and neutral manner" starting in March 2008.[161] If manufacturers choose this option, however, they must make "adequate provision … for dissemination of the approved or permitted package labeling in connection with the broadcast presentation."[162] To fulfill the adequate provision requirement, manufacturers may include four additional facts in the broadcast: a toll-free number, a reference to a contemporaneous print advertisement or readily available pamphlet, a website URL and a message to check with their doctor/pharmacist as a further source of information.[163] The advertising content must be consistent with the product's labeling.[164]

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[154] Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, § 906(a) (2007) (to be codified as amended at 21 U.S.C. § 352(n)).

[155] FDA, Draft Guidance for Industry: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements 2-6 (Jan. 2004).

[156] 21 C.F.R. § 202.1(j)(4).

[157] *Id.* § 314.640.

[158] FDAAA, Pub. L. No. 110-85, § 901(d)(2) (2007) (to be codified at 21 U.S.C. § 353B).

[159] *Id.*

[160] 21 C.F.R. § 202.1(e)(1); Paula A. Miller, A Linguistic Look at a Legal Issue: Prescription Drug Television Advertising 4 (2001) (unpublished Masters' thesis, San Diego State University, on file with San Diego State University library).

[161] FDAAA, Pub. L. No. 110-85, § 901(d)(3) (2007) (to be codified as amended at 21 U.S.C. § 352(n)).

[162] FDA, Guidance for Industry: Consumer-Directed Broadcast Advertisements 1-2 (Aug. 1999) (citing 21 C.F.R. § 202.1(e)(1)).

[163] *Id.* at 2-3; Miller, *supra* note 160, at 4.

[164] FDA, Guidance for Industry: Consumer-Directed Broadcast Advertisements, *supra* note 162, at 2.

2. *Device Advertising*

Restricted device advertising cannot have false or misleading content, and must carry particular accompanying statements, including the device's established name and a "brief statement" of the intended uses, relevant "warnings, precautions, side effects and contraindications." [165] Generally, device advertisements need not be pre-approved.[166] Nonetheless, a manufacturer's advertising and promotion for a device must be based *only* on the information in the PMA approval order or 510(k) clearance order, as applicable.[167]

FDA released a Draft Guidance to flesh out the "brief statement" requirement in broadcast advertising.[168] It indicates that restricted device manufacturers may fulfill the brief statement requirement through an approach that: 1) discloses the most serious and most commons risks associated with the device in the audio or audio and visual components of the presentation; and 2) makes "adequate provision" for the "approved or permitted package labeling."[169] The adequate provision guidelines are essentially the same as those for prescription drug advertising, providing for reference to a toll-free number, print advertisements or brochures, website URLs, and physicians as sources of further information.[170] For investigational devices, the regulations prohibit pre-approval promotion or test marketing, claims of safety or efficacy, and commercialization by charging for an investigational device "a price larger than necessary to recover costs."[171]

A manufacturer may refer to a device that has been the subject of an approved PMA as "FDA-approved" in its promotional materials.[172] A manufacturer who obtains clearance of a device via the 510(k) process, however, may not make "[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification regulations."[173] On a related note, the regulations pertaining to analyte specific reagents (ASRs) prohibit any and all promotional materials from discussing "analytical or clinical performance" because they have no 510(k) clearance or PMA approval.[174]

3. *Pharmacy Compounding and Advertising Restrictions*

The major provision related to pharmacy compounding advertisements is discussed in the context of *Western States*, below.

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[165] 21 U.S.C. § 352(q).

[166] *Id.* § 352(r).

[167] 21 C.F.R. § 814.80.

[168] FDA, Draft Guidance for Industry and FDA, Consumer-Directed Broadcast Advertising for Restricted Devices 3-5 (2004).

[169] *Id.* at 3.

[170] *Id.* at 3-4.

[171] 21 C.F.R. § 812.7. Certain devices intended for pediatric use are exempted from the prohibition on charging a price beyond costs. FDAAA, Pub. L. No. 110-85, § 303(a) (2007) (to be codified as amended at 21 U.S.C. § 360j(m)); *see also* FDA, Guidance for Industry and FDA Staff: Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects 1, 3 (Mar. 19, 1999).

[172] *See* Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, § 421, 111 Stat. 2325, 2380 (1997) (codified as amended at 21 U.S.C. § 331(l)) (striking former provisions of the FDCA prohibiting mention of device PMA approval).

[173] 21 C.F.R. § 807.97.

[174] *Id.* § 809.30.

E. *"Off-label" Speech*

Off-label use occurs when a physician prescribes an approved product for a use that is not indicated in its labeling or is otherwise unapproved by FDA.[175] According to FDA, manufacturer promotion for an off-label use constitutes misbranding (because the product is not labeled for the promoted intended use).[176] Promotion of off-label uses is prohibited.[177] The law is less clear on non-promotional speech concerning off-label uses.

In its 1997 Guidance on industry-supported scientific educational programs, FDA prohibited manufacturer-sponsored programs from including discussion of off-label uses about the manufacturer-sponsor's products.[178] To determine if the program was manufacturer-sponsored, FDA adopted a fact-laden inquiry examining the degree of manufacturer influence.[179] Relevant factors included whether the manufacturer chose speakers and topics of discussion; whether the company made adequate disclosures about its funding and conflicts of interest; the focus of the program; the relationship between the provider and the supporting company; audience selection; opportunities for discussion; ancillary promotional activities; whether involved entities were financially tied to the manufacturers; and whether further information was disseminated.[180] A written agreement relinquishing control of the event to the provider allowed the manufacturer "safe harbor" protection from enforcement action.[181] Moreover, the Guidance also prohibited dissemination of materials concerning off-label uses after the program, including reprints and other "enduring materials," except in response to an unsolicited request.[182]

Section 401 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), which recently ceased to be effective due to a sunset clause, allowed dissemination of reprints and reference publications about off-label uses if the following conditions were met: 1) the materials were directed to physicians, group health plans, pharmacy benefit managers, government bodies or insurers; 2) the product had an approved NDA or authorized device application from the premarket approval process for at least one use; 3) the information distributed was not derived from another manufacturer's testing; 4) the manufacturer submitted a supplemental NDA for the new use within sixty days or certified that appropriate studies were completed or planned; 5) progress reports were submitted if the studies were in progress; and 6) the manufacturer kept records and reported to FDA every

[175] A. Elizabeth Blackwell & James M. Beck, *Drug Manufacturers' First Amendment Right to Advertise & Promote Their Products for Off-Label Use: Avoiding a Pyrrhic Victory*, 58 FOOD & DRUG L.J. 439, 440 (2003).

[176] 21 U.S.C. §§ 321(n), 352; 21 C.F.R. § 202.1(e)(4)(I)(A); Blackwell & Beck, *supra* note 175, at 441, 443-444.

[177] *E.g.,* 21 C.F.R. § 202.1(e)(4)(i)(a).

[178] FDA, Guidance for Industry: Industry-Supported Scientific and Educational Activities (1997), *reprinted in* Notice Concerning Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074, 64,093-94, 64,096 (Dec. 3, 1997); *see also* Jeffrey N. Gibbs, *First Amendment Limits on Regulating Information: An Initial Reaction to the Washington Legal Foundation Case*, 53 FOOD & DRUG L.J. 597, 597 (1998) (noting FDA's tough stance on off-label materials in/at manufacturer-sponsored programs).

[179] 62 Fed. Reg. at 64,095.

[180] *Id.* at 64,095-64,099.

[181] *Id.* at 64,099.

[182] *Id.* "Enduring materials," include textbooks, journal articles, etc. Daniel J. Gilman, *Protecting Protected Speech: First Amendment Taxonomy & the Food and Drug Administration's Regulation of "Enduring Materials*," 58 FOOD & DRUG L.J. 463, 463 (2003); *Drug Firms Want FDA Regs Allowing Journal Article Dissemination*, FDA WEEK, (Sept. 7, 2007) (discussing that the FDAMA provision recently ceased to be effective due to a sunset clause).

six months regarding who received the reprints/reference publications.[183] Failure to comply with these conditions could result in enforcement action in the form of required corrective speech.[184]

FDAMA section 401 was struck down in *Washington Legal Foundation*.[185] Subsequently, FDA interpreted the provision to constitute a safe harbor for manufacturer off-label speech: material distribution in compliance with these conditions will not be used as evidence of a "new use," and failure to comply with it is not an independent violation of the FDCA.[186] Moreover, FDA indicated intent to enforce its policy on a case-by-case basis. A subsequent FDA letter stated that a typical enforcement action will arise from a *combination* of disseminating enduring materials with violative activity, whereas it is "unlikely" that FDA will bring enforcement action from the mere fact of distribution of enduring materials.[187]

F. *Drugs Undergoing the Approval Process*

FDA prohibits manufacturers from "represent[ing] in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation" or "otherwise promot[ing] the drug."[188] FDA does, however, note that it does not intend to "restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media."[189]

FDA permits speech about unapproved drugs in scientific and educational settings, particularly "company sponsored symposia which offer an opportunity for scientific dialogue" and all scientific/medical publication.[190] Nevertheless, the symposia activities must be limited to educational information only. Exhibits in "educational" areas of symposia are allowed generally, while the rules for exhibits in the commercial exhibit areas are less clear, and will depend on whether the exhibit is scientifically or commercially oriented.[191] At least in commercially oriented exhibit booths, sponsors cannot disseminate symposia reprints before product approval or distribute "educational materials" other than proposed labeling.[192]

Sponsors can utilize one of two safe harbors to discuss forthcoming drugs in a promotional manner: 1) "institutional advertisements," which declare that the

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[183] FDAMA, Pub. L. No. 105-115, § 401, 111 Stat. 2296, 2328 (1997) (codified at 21 U.S.C. §§ 360aaa-360aaa-6) (ceased to be effective due to a sunset clause); *see also* O'REILLY, *supra* note 9, § 15:17.

[184] FDAMA, Pub. L. No. 105-115, § 401, 111 Stat. 2296, 2328 (1997) (codified at 21 U.S.C. §§ 360aaa-360aaa-6) (ceased to be effective due to a sunset clause).

[185] Washington Legal Found. v. Henney, 56 F. Supp. 2d 81, 84 (D.D.C. (1999)).

[186] Washington Legal Found. v. Henney, 202 F.3d 331, 332 (D.C. Cir. (2000)); Decision in Washington Legal Found. v. Henney, 65 Fed. Reg. 14,286, 14,287 (Mar. 16, 2000).

[187] Comments of Boston Scientific Corp. in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C29, at 9-10 (Sept. 11, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091302/80027ac2.pdf (citing Letter from Margaret M. Dotzel, Associate Commissioner for Policy, FDA to Daniel J. Popeo and Richard A. Samp, Washington Legal Foundation, Docket No. 01P-0250 (Jan. 28, 2002), at 6).

[188] 21 C.F.R. § 312.7(a).

[189] *Id.*

[190] Evans & Friede, *supra* note 48, at 401-403 (citing Letter concerning Reissuance of Pre-Approval Promotion Guidance, from FDA Div. of Drug Advertising and Labeling to Industry (Aug. 1986) [hereinafter Promotion Guidance Letter]).

[191] DAVID J. BLOCH ET AL., THE FUNDAMENTALS OF LIFE SCIENCE LAW: DRUGS, DEVICES, AND BIOTECH 190 (2007); *see also* Comments of PhRMA in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C46, at 39-40 (Sept. 13, 2002), http://www.fda.gov/ohrms/DOCKETS/dailys/02/Sep02/091602/80027d32.pdf.

[192] Evans & Friede, *supra* note 48, at 401 (citing Promotion Guidance Letter, *supra* note 190).

company is "conducting research in a certain therapeutic area" but cannot not include the drug name; and 2) "Coming Soon" advertisements, which announce only the established and proprietary names of the drug but may not make any claims about its safety, effectiveness, or uses.[193] After choosing one of these options, the company may not switch to the other.[194] Moreover, only the institutional format is allowed for drugs anticipated to require a "black box" warning.[195]

III. RELEVANT FIRST AMENDMENT DOCTRINE

As background for discussing the First Amendment constraints on FDA, this section outlines the legal frameworks governing the following: 1) commercial speech; 2) noncommercial speech; 3) nonexpressive conduct; 4) speech constituting unlawful behavior; 5) compelled speech; and 6) prior restraints.[196] Each doctrine will be outlined in turn.

A. *Commercial Speech*

The commercial speech regime is particularly relevant to FDA because much of the speech it encounters falls into this category.[197] This section delineates 1) the definition of commercial speech, and 2) the standard for analyzing restrictions of commercial speech (the *Central Hudson* test).

1. *Defining Commercial Speech*

The Supreme Court noted commercial speech must be "distinguished by its content."[198] Speech is commercial if it: 1) proposes a commercial transaction; or 2) fulfills the factors adopted in *Bolger v. Youngs Drug Products*.[199] Speech that meets the first condition essentially provides, "I will sell you the X [product] at the Y price."[200] Second, if speech does not propose a commercial transaction, courts will examine the three *Bolger* factors to determine if the speech nonetheless is commercial speech: 1) whether it constitutes an "advertisement[];" 2) whether it refers to a "specific product"; and 3) whether the speaker has an "economic motivation"

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[193] *Id.* (citing Promotion Guidance Letter, *supra* note 190); Madeleine M. Jester, *Pre-Approval Promotion: Conforming to FDA Regulation* (presentation) (Apr. 1999), http://www.cnahealthpro.com/amt/preappro.html.

[194] *See* Comments of Pfizer in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C32, at 96 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027f2d.pdf (citing Promotion Guidance Letter, *supra* note 190).

[195] *Id.* (citing Promotion Guidance Letter, *supra* note 190).

[196] *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 360 (2002); United States v. United Foods, 533 U.S. 405, 410 (2001); United States v. O'Brien, 391 U.S. 367, 377 (1968); Near v. Minnesota, 283 U.S. 697, 713-722 (1931); Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51, 62 (D.D.C. (1998)); Nicole Endejann, *Is the FDA's Nose Growing?: The FDA Does Not "Exaggerate Its Overall Place in the Universe" When Regulating Speech Incident to "Off-Label" Prescription Drug Labeling & Advertising*, 35 AKRON L. REV. 491, 497 (2002); Evans & Friede, *supra* note 48, at 416.

[197] Richard A. Samp, *Courts Are Arriving at a Consensus on Food and Drug Administration Speech Regulation*, 58 FOOD & DRUG L.J. 313, 313 (2003) ("[A] consensus is emerging that in most cases, FDA restrictions on manufacturer speech about their products are going to be judged under commercial speech standards.").

[198] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 761 (1976).

[199] 463 U.S. 60 (1983); *see also* City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 422 (1993) (discussing *Bolger*). Commentators disagree as to whether *Bolger* is still valid. Because it has not been overruled directly, this article assumes that *Bolger* still constitutes binding precedent, but acknowledges the lively debate on this issue.

[200] Va. Pharmacy, 425 U.S. at 761.

for the speech.[201] The Court has suggested strongly that speech fulfilling all three *Bolger* factors is commercial speech, but also "express[ed] no opinion" as to whether fulfillment of all three factors is *necessary* for speech to be commercial.[202] In any event, economic motivation alone is insufficient to render speech commercial.[203]

When commercial and noncommercial speech are presented together, the Court applies special rules. When commercial speech is "inextricably intertwined" with noncommercial speech, the heightened test for noncommercial speech applies.[204] For example, the strict scrutiny framework applies when the commercial aspect of the speech is a legally required statement.[205] *Fox* suggested that the commercial speech framework would apply as to other speech with commercial speech components.[206] The Court recently passed on an opportunity to clarify the scope of this rule by dismissing the writ of certiorari in *Nike v. Kasky* as improvidently granted. This case would have considered whether Nike's factual statements about its labor practices—described by the Court as a "blending of commercial speech, noncommercial speech and debate on an issue of public importance" —would be regulated as commercial speech.[207]

2. *First Amendment Inquiry for Commercial Speech Restrictions*

In *Virginia Pharmacy*, the Supreme Court established that commercial speech enjoys First Amendment protection, though of a "different [lesser] degree" than noncommercial speech.[208] It did not establish a test for delineating the scope of that protection, however. Instead, the Court invalidated a "highly paternalistic" ban on pharmacy advertising, noting that the government could not justify a ban on such speech to protect pharmacy professionalism or the public health.[209] The Court expressed a strong preference for disclosure instead of suppression, adopted the assumption that people "will perceive their own best interests if only they are well enough informed," and identified "open[ing] the channels of communication rather than clos[ing] them" as the "best means" to the end of a knowledgeable consumer population.[210] The Court also expressed disdain for arguments that audiences cannot comprehend truthful information.

Subsequently, in *Central Hudson*, the Court considered and struck down a ban on promotional advertising by electrical utilities.[211] It also adopted the governing

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[201] Bolger, 463 U.S. at 66-67. *Bolger* analyzed whether general drugstore flyers, specific product flyers and informational pamphlets for condoms were commercial speech. *Id.* at 62. The Court found that the flyers were "core" commercial speech, but reasoned that the informational pamphlets could not be "characterized merely as proposals to engage in commercial transactions." *Id.* at 66. Ultimately, the pamphlets were found to be commercial speech. *Id.* at 68.

[202] *Id*. at 67 n.13, 68 n.14.

[203] *See* Va. Pharmacy, 425 U.S. at 761; Bd. of Trustees of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 482 (1989) (citing to a variety of cases covering mediums of expression including newspapers, political contributions, religious literature, and motion pictures). *Virginia Pharmacy* emphasizes the protection of speech concerning economic considerations in the context of labor disputes. 425 U.S. at 762.

[204] *Fox*, 492 U.S. at 474; Riley v. Nat'l Fed'n of Blind of N.C., Inc., 487 U.S. 781, 796 (1986).

[205] *Fox*, 492 U.S. at 474; *Riley*, 487 U.S. at 795 (analyzing state statute that required fundraisers to disclose to potential donors the percentage of the previous year's donations that actually went to the charity); Metromedia, Inc. v. City of San Diego, 453 U.S. 490, 540 (1981) (Brennan, J., concurring).

[206] *Fox*, 492 U.S. at 474.

[207] 539 U.S. 654, 663 (2003).

[208] *Va. Pharmacy*, 425 U.S. at 764-768, 772 n.24.

[209] *Id* at 764-769.

[210] *Id*. at 769-770.

[211] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 572 (1980).

framework for determining the constitutional validity of a commercial speech restriction:

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must *concern lawful activity* and *not be misleading* ["prong one"]. Next, we ask whether the *asserted governmental interest is substantial* ["prong two"]. If both inquiries yield positive answers, we must determine whether the regulation *directly advances* the governmental interest asserted ["prong three"], and whether it is *not more extensive than is necessary* to serve that interest ["prong four"].[212]

The governmental body seeking to impose the restriction bears the burden of justifying it under this test.[213] The Court has continued to develop the *Central Hudson* test since its adoption. The current status of each prong is discussed in the following subsections.

a. Prong One: Illegal Underlying Activity, False and Misleading

The Court has continued to use the *Pittsburgh Press* rule to determine if speech concerns a lawful activity.[214] This rule allows prohibition of speech where the underlying activity to which it refers is itself illegal.[215] In *Pittsburgh Press*, the Court upheld a ban on sex-based employment listings in a Pittsburgh newspaper.[216] Though the Court temporarily extended this rule to permit bans of speech about any activity which itself could be outlawed, the Court since has returned to the *Pittsburgh Press* interpretation of prong one.[217] The prohibition against false advertising has not changed since *Central Hudson*, with subsequent cases typically citing *Central Hudson* for prong one.[218]

The Court has developed its doctrine on the misleading aspect of prong one. First, the Court has provided that the government has the burden of proof to

[212] *Id.* at 566 (emphasis added). Commentators and individual members of the Supreme Court have debated whether the *Central Hudson* test is the appropriate framework for analyzing commercial speech. In *Western States*, however, the Court applied the *Central Hudson* test as "an adequate basis for decision" but recognized several Justices' doubts about its propriety. Thompson v. W. States Med. Ctr., 535 U.S. 357, 367-68 (2002) (citing to various individual and joint, non-majority opinions critiquing the *Central Hudson* test).

[213] *See Cent. Hudson*, 447 U.S. at 570; Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 71 n.20 (1983).

[214] *See, e.g.*, Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S.489, 496 (1982) (finding that the commercial speech at issue promoted illegal drug use and therefore could be banned consistent with *Pittsburgh Press* and *Central Hudson*).

[215] Pittsburgh Press Co. v. Human Relations Comm'n, 413 U.S. 376, 388 (1973)).

[216] *Id.* at 389.

[217] *Compare* Posadas de P.R. Assocs. v. Tourism Co. of P.R., 478 U.S. 328 (1986) (reasoning that, because the government could wholly *ban* casino gambling, it must also have the lesser power to ban commercial speech *about* casino gambling and upholding a Puerto Rico statute banning casino advertising to its residents) *with* Greater New Orleans Broad. Ass'n, Inc. v. United States, 527 U.S. 173, 182 (1999) ("[W]e had rejected that argument that the power to restrict speech about certain socially harmful activities was as broad as the power to prohibit such conduct."); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 497 n.7 & 513 (1996) (plurality opinion) (discussing the illegality prong and noting "As the entire Court apparently now agrees, the statements in the *Posadas* opinion … are no longer persuasive.").

[218] *See, e.g.,* Ibanez v. Fla. Dep't. of Bus. & Prof'l Regulation, Bd. of Accountancy, 512 U.S. 136, 142 (1994) (citing *Cent. Hudson*, 447 U.S. at 557, 566).

show speech is misleading.[219] Second, the Court has recognized two categories of misleading speech: "potentially" misleading speech and "inherently" misleading speech—which disclaimers or qualifying language cannot render nonmisleading or which "experience has proved [to be] subject to abuse."[220] The government may totally ban inherently misleading speech.[221] Potentially misleading speech cannot be subject to a total ban; instead full *Central Hudson* analysis applies.[222] Thus, regulators must, as a first resort, consider the use of disclaimers, warnings, or explanations to render the speech nonmisleading. Only if these measures are ineffectual can the government pursue a ban.[223] Finally, whether the government contends speech is inherently or potentially misleading, it bears the burden of proving that the speech is in fact misleading.[224] The Supreme Court does not allow "rote invocation" of the phrase "potentially misleading" to justify speech bans, but must show disclaimers are inappropriate.[225]

To determine whether a communication is misleading, Supreme Court precedent requires consideration of the message's audience.[226] *Edenfield* invalidated a ban on accounting advertising because the audience was comprised of "sophisticated and experienced business executives," but *Ohralik* upheld a ban on in-person legal solicitation where the audience consisted of vulnerable accident victims.[227]

The Court's jurisprudence reveals that bans are tolerated only where the government makes a substantial showing justifying the ban. In *Friedman*, the Supreme

[219] Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 646 (1985) (discussing the government's burden to distinguish the "helpful from the misleading"). The government may satisfy this burden by showing a certain practice, for example in-person solicitation of legal services, is "more often than not, … injurious." Edenfield v. Fane, 507 U.S. 761, 776 (1993); Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 466 (1978)).

[220] *In re* R.M.J., 455 U.S. 191, 203, 206-207 (1982); Revo v. Disciplinary Bd. of N.M., 106 F.3d 929, 933 (10th Cir. (1997)) ("For a particular mode of communication to be inherently misleading, it must be incapable of being presented in a way that is not deceptive."). According to the Center for Constitutional Rights, speech found to be "inherently misleading," includes "speech that is delivered in a fashion that is inherently coercive, speech that is inherently devoid of meaning, speech that has been empirically found to be deceptive in practice, speech that has historically been regarded as deceptive, speech that can only be understood with esoteric knowledge available to professional insiders … , speech making general claims about professional services that are inherently individualized (as to both appropriateness for the consumer and quality of the provider …) and, finally, speech where common sense indicates that there is a good chance of confusion … ." Comments of the Ctr. for Constitutional Rights in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C53, at 6-7 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d3e.pdf.

[221] *R.M.J.*, 455 U.S. at 203; *see also* Friedman v. Rogers, 440 U.S. 1, 14, 16 n.17 (1979) (history of abuses in optometry trade name usage justified total ban).

[222] *See Ibanez*, 512 U.S. at 146; *R.M.J.*, 455 U.S. at 203.

[223] *R.M.J.*, 455 U.S. at 203; Bates v. State Bar of Ariz., 433 U.S. 350, 375 (1977).

[224] *See Ibanez*, 512 U.S. at 146.

[225] *Id.*; *see also* Thompson v. W. States Med. Ctr., 535 U.S. 357, 376 (2002).

[226] Comments of AdvaMed in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C49, at 3 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d39.pdf; Comments of Am. Soc'y of Clinical Oncology in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C52, at 2 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d3d.pdf; Comments of Hyman, Phelps, and McNamara in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C43, at 23 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d2f.pdf; Comments of King and Spaulding in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C38, at 16-17 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d24.pdf; Comments of Nat'l Venture Capital Ass'n in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C47, at 6 (Sept. 13, 2002), http://www.fda.gov/ohrms/DOCKETS/dailys/02/Sep02/091602/80027d34.pdf; Comments of Pfizer, *supra* note 194, at 56; Comments of PhRMA, *supra* note 191, at 21.

[227] *See* Edenfield v. Fane, 507 U.S. 761, 775-76 (1993); Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 449, 465 (1978).

Court held that Texas could ban the use of trade names in the optometry field as misleading, where the state presented extensive evidence that trade names had been used in an actually misleading way.[228] In *Bates*, the Court rejected the assertion that attorney advertising on the whole is inherently misleading.[229] The *Ibanez* Court overturned the state board's ban and enforcement action with respect to an attorney advertisement that included a (truthful) reference to the attorney's credentials as a CPA.[230]

b. Prong Two: Substantial Governmental Interest

The government is typically able to fulfill prong two, though there are a few exceptions. Generally, the government must show that "the harms it recites are real" to fulfill prong two.[231] In the First Amendment context, courts will not consider "hypothesized" justifications, which are rationalizations put forth by the Court but not asserted by the government.[232]

The Court has classified as "substantial" a number of articulated government interests: avoiding commercial exploitation of students and maintaining security in *Fox*; aiding parents in keeping offensive mail from children in *Bolger*; preserving CPA independence, prevention of over-reaching and maintenance of privacy in *Edenfield*; safeguarding the professional reputation of lawyers and respecting personal privacy in *Went For It*; promoting racially-integrated housing in *Linmark*; traffic safety and aesthetics in *Metromedia*; preventing alcoholism in *Rubin*; and supporting lottery policies of various states in *Edge Broadcasting*.[233] In contrast, only a handful of interests have been deemed insubstantial: shielding adult recipients from offensive mail in *Bolger*;[234] facilitation of state liquor laws in *Rubin*;[235] and prevention of litigation in *Zauderer*.[236]

Thus, the Court tends to evaluate asserted governmental interests on their individual facts and rarely finds them to be insubstantial. This prong of the *Central Hudson* test is not typically dispositive, particularly in the food and drug field where the government "clear[ly]" has a substantial interest in "ensuring the public availability of safe, effective and properly labeled medicines."[237]

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[228] Friedman v. Rogers, 440 U.S. 1, 12-17 (1979).

[229] Bates v. State Bar of Ariz., 433 U.S. 350, 372-373 (1977). In *Zauderer*, the Court did permit a disclaimer policy for attorney advertising. Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 653 (1985).

[230] Ibanez v. Fla. Dep't. of Bus. & Prof'l Regulation, Bd. of Accountancy, 512 U.S. 136, 146-149 (1994).

[231] *Edenfield*, 507 U.S. at 770-771.

[232] Thompson v. W. States Med. Ctr., 535 U.S. 357, 373 (2002). Because the government has the burden of proof as to each prong of the *Central Hudson* test, it must identify the substantial interest(s) its regulation advances. *See id.* at 373-374.

[233] Fla. Bar v. Went For It, 515 U.S. 618, 625 (1995); Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995); *Edenfield*, 507 U.S. at 769-770; United States v. Edge Broad. Co., 509 U.S. 418, 426 (1993); Bd. of Trustees of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 475 (1989); Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 73 (1983); Metromedia, Inc. v. City of San Diego, 453 U.S. 490, 508 (1981); Linmark Assocs., Inc. v. Willingboro Twp., 431 U.S. 85, 94 (1977).

[234] *Bolger*, 463 U.S. at 71.

[235] *Rubin*, 514 U.S. at 486 (reasoning that states can enact their own legislation with regard to alcohol labeling and there is no evidence they need federal help on this matter).

[236] Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 643 (1985) (arguing that litigation is not necessarily a bad thing and can help redress grievances, and finding that a state may not interfere with citizens' access to the courts by denying them information about available lawyers). It is also noteworthy that no substantial interest was asserted in *R.M.J.*, hence this speech restriction failed because the state did not carry its burden as to prong two. 455 U.S. 191, 205 (1982).

[237] Eve E. Bachrach, *Current Developments in Commercial Free Speech & Government Regulation of Labeling & Advertising of Over-the-Counter Drugs*, 45 FOOD DRUG COSM. L.J. 223, 230 (1990).

c. Prong Three: Direct Advancement of Governmental Interest

To satisfy the third prong, the government must produce evidence showing that the regulation directly advances its goals and demonstrate that it does so in a consistent fashion. First, under *Edenfield*, the government must present evidence showing that the speech restriction will "in fact alleviate [the harms] to a material degree;" it cannot rely on "mere speculation or conjecture."[238] For example, in *Edenfield*, the Court invalidated a ban on solicitation by CPAs because the state board presented no studies or anecdotal evidence supporting its interests.[239]

Second, under *Rubin* and *Greater New Orleans*, the speech regulation must meet certain standards of consistency and rationality to survive prong three. In *Rubin*, the Court found the government's ban on beer advertisements did not satisfy prong three because the scheme's "overall irrationality" precluded it from achieving its goal (preventing beer "strength wars").[240] The speech ban was irrational because the law *allowed* alcohol content labels on wine, beer content information in advertisements, and use of the term "malt liquor."[241] *Greater New Orleans* found a ban on casino advertising to be "so pierced by exceptions and inconsistencies that the Government cannot hope to exonerate it," because only certain types of casino ads were prohibited while others allowed.[242]

Since *Edenfield*, the Court has upheld bans where the government presented evidence justifying its ban. In *Edge Broadcasting*, the Court sustained a ban on radio lottery ads aimed at furthering North Carolina's anti-gambling policy where the government presented evidence that the ban would result in an eleven percent reduction in the number of North Carolinians who would hear the gambling advertisements.[243] Similarly, in *Went For It*, the Court found that a 106-page two-year study accompanied by anecdotal evidence met the third prong's evidentiary requirements, and thus upheld support Florida's ban on targeted solicitation of legal services from accident victims and their families within a thirty day period after the accident.[244] In *44 Liquormart*, the Court invalidated Rhode Island's ban on liquor price advertising where the state made no findings of fact and had no "evidentiary support whatsoever."[245]

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[238] 507 U.S. 761, 767, 770-771 (1993).

[239] *Id.* at 771.

[240] Rubin v. Coors Brewing Co., 514 U.S. 476, 488-889 (1995).

[241] *Id.*

[242] Greater New Orleans Broad. Ass'n, Inc. v. United States, 527 U.S. 173, 190 (1999).

[243] United States v. Edge Broad. Co., 509 U.S. 418, 427, 432 (1993).

[244] Fla. Bar v. Went For It, 515 U.S. 618, 628-629 (1995).

[245] 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 505-506 (1996) (plurality opinion). *Tennessee Secondary* did not change the generally applicable evidentiary requirement for prong three. There, the Court held that an anti-recruiting rule, applicable to high schools that voluntarily joined an athletic association, did not violate the First Amendment. Tenn. Secondary Sch. Athletic Ass'n v. Brentwood Acad., 127 S. Ct. 2489, 2495-96 (2007). The majority opinion stated: "We need no empirical data to credit [the] common-sense conclusion that hard-sell tactics driven at middle school students could lead to exploitation." *Id.* Five Justices made clear, however, that the case was dependent on the fact that the school had voluntarily joined the athletic association, and did not affect nor depend on the *Ohralik* or *Edenfield* line of cases. *See id.* at 2498-99 (Kennedy, J., concurring in the judgment); *id.* at 2499 (Thomas, J.., concurring in the judgment). Even the four Justice plurality that discusses these cases distinguishes *Edenfield* and emphasizes its conclusion does not apply to "conventional commercial speech" or commercial speech that "appeals to the public at large." *See id.* at 2493, 2494 (plurality opinion). Thus, the isolated statement crediting common sense notions rather than requiring evidence is inapplicable to standard *Central Hudson* analysis.

The third prong does not require an examination of the regulation's application as to "a single person or entity" —i.e., an individual radio station—but instead as to the general population of speakers.[246] Nonetheless, speech restrictions that suppress the speech of one group of speakers while allowing virtually identical messages from others "for no convincing reason" are "in serious tension" with the First Amendment.[247]

d. Prong Four: Not More Extensive Than Necessary

Western States explained the fourth prong as follows: "In previous cases addressing this final prong of the *Central Hudson* test, we have made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government *must* do so."[248] More specifically, "regulating speech must be a last—not first—resort."[249] Thus, the fourth prong is not fulfilled if "numerous and obvious less-burdensome alternatives" exist.[250]

In *44 Liquormart*, the presence of alternatives to a prohibition on ads featuring alcohol prices—including educational campaigns, higher prices, taxes and per capita purchase caps—warranted invalidation of the ban.[251] Similarly, in *Greater New Orleans*, the government failed to satisfy prong four because of alternatives to the ban on gambling advertisements, such as prohibition of -gambling on credit, betting and pot limits, ATM location controls, location restrictions, and licensing requirements.[252] In *Peel*, the government could not sustain its fourth prong burden as to a ban on certain attorney advertising, because alternatives like disclaimers were available.[253] Finally, the Court recognized alternatives to the ban on beer advertising in *Rubin*, because the government could instead directly limit alcohol content of beers, prohibit marketing efforts emphasizing high alcohol strength and limit its labeling ban only to malt liquor.[254]

Finally, the state will fail the fourth prong if it singles out commercial speech for a selective ban.[255] In *Discovery Network*, a ban of only commercial speech newspaper items in community news racks was found to fail the fourth prong because the differences in commercial and noncommercial speech were not relevant to the asserted state interests in safety and aesthetics, i.e., there was no reason to think that commercial speech contributed more than noncommercial speech to these problems.[256]

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[246] United States v. Edge Broad. Co., 509 U.S. 418, 427 (1993)

[247] *Greater New Orleans*, 527 U.S. at 191, 193-94.

[248] Thompson v. W. States Med. Ctr., 535 U.S. 357, 371 (2002). *Fox* previously provided that prong four did not require the government to use the least restrictive means possible to achieve its goals. Bd. of Trustees of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 476-480 (1989). Instead, it provided that the government must establish a "reasonable fit" between its goals and means, i.e., the means must be "narrowly tailored" to achieve the desired end. *Id. Fox* also stated that the presence of regulatory alternatives to the speech restriction would not automatically invalidate the regulation. *Id.* at 478. The *Western States* interpretation of prong four, however, suggests the alternatives to the speech regulation at issue are highly relevant, and in fact, dispositive. Further, other cases subsequent to *Fox* demonstrate that courts must inquire into alternatives to a speech restriction and employ an analysis akin to "least restrictive means." *See, e.g.*, City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 418 n.13 (1993).

[249] *Western States*, 535 U.S. at 373.

[250] *Discovery Network*, 507 U.S. at 418 n.13.

[251] 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 507 (1996) (plurality opinion).

[252] *Greater New Orleans*, 527 U.S. at 192.

[253] Peel v. Attorney Registration & Disciplinary Comm'n of Ill., 496 U.S. 91, 110-11 (1990).

[254] Rubin v. Coors Brewing Co., 514 U.S. 476, 491 (1995).

[255] *Discovery Network*, 507 U.S. at 424, 428.

[256] *Id.*

B. *Regulation of Noncommercial Speech*

Core noncommercial speech consists of communications having "literary, artistic, political or scientific value," such as academic speech.[257] The general rule is that noncommercial speech can only be restricted if the government can satisfy "strict scrutiny," i.e., the restriction is "narrowly tailored to promote a compelling [g]overnment interest."[258] Narrow tailoring requires the legislature to use the "least restrictive means" to serve its purpose.[259] Furthermore, where the government *intends* content-based suppression to shield listeners, "the general rule is that the right of expression prevails, even where no less restrictive alternative exists."[260] Therefore, content-based restrictions on noncommercial speech are subjected to a demanding test and usually fail.[261]

More lax standards are available for noncommercial speech restrictions that do not differentiate on the basis of content.[262] Time, place and manner restrictions are valid if: 1) they are "justified without reference to the content" of the speech; 2) "narrowly tailored" to serve a "*significant* governmental interest;" and 3) "leave open ample alternative channels" to convey the message.[263] The time, place and manner test does *not* include a least-restrictive-means requirement, and hence is less demanding than strict scrutiny.[264] This test has been called "substantially similar" to *Central Hudson*.[265]

C. *Regulation of Speech Incidental to Regulation of Conduct*

Different tests exist for *expressive* and *non-expressive* conduct.[266] If the government's objective in regulating speech targets the "communicative nature of the conduct," then ordinary First Amendment analysis applies.[267] Where the government interest is *unrelated* to suppression of the expression (and therefore applies to "non-expressive conduct"), the *O'Brien* test applies.[268] In that case, the defendant burned his draft card in violation of a federal statute, and argued that his conduct was protected as "symbolic speech."[269] The problem inherent in this logic was that defendant's actions combined "speech and non-speech elements" and here the

[257] Miller v. California, 413 U.S. 15, 34 (1973); Keyishan v. Bd. of Regents, 385 U.S. 589, 604 (1967).

[258] *See, e.g.,* United States v. Playboy Entm't Group, Inc., 529 U.S. 803, 813 (2000); Evans & Friede, *supra* note 48, at 380-381.

[259] *Playboy*, 529 U.S. at 813, 824.

[260] *Id*. at 813.

[261] Miller v. Johnson, 515 U.S. 900, 920 (1995); Evans & Friede, *supra* note 48, at 381.

[262] Ward v. Rock Against Racism, 491 U.S. 781, 800 n.6 (1989).

[263] Clark v. Cmty. for Creative Non-Violence, 468 U.S. 288, 293 (1984) (emphasis added).

[264] *Ward*, 491 U.S. at 797.

[265] Bd. of Trustees of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 477 (1989) (quoting Clark, 468 U.S. at 288).

[266] *See* Texas v. Johnson, 491 U.S. 397, 407 (1989) (noting that First Amendment analysis differs depending on whether the government's purposes are unrelated to the suppression of expression); *see also* Rumsfeld v. Forum for Academic & Inst. Rights, Inc., 547 U.S. 47, 65-67 (2006) (quoting United States v. Albertini, 472 U.S. 675, 689 (1985) ("If combining speech and conduct were enough to create expressive conduct, a regulated party could always transform conduct into 'speech' simply by talking about it."); Comments of Pfizer, *supra* note 194, at 51 (classifying the differing tests as applicable to "non-expressive" and "expressive" conduct, respectively).

[267] *Johnson*, 491 U.S. at 406.

[268] United States v. O'Brien, 391 U.S. 367, 367 (1968); *see also Johnson*, 491 U.S. at 406-407; Comments of Pfizer, *supra* note 194, at 51.

[269] *O'Brien*, 391 U.S. at 370, 376.

conduct was non-expressive.[270] These "incidental" restrictions on non-expressive conduct are subject to the following test:

> [A] government regulation is sufficiently justified if it is within the constitutional power of the Government; if it furthers an important or substantial governmental interest; if the governmental interest is unrelated to the suppression of free expression; and if the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest.[271]

Forum for Academic and Institutional Rights provides further clarification on the *O'Brien* test's fourth prong: an incidental burden on speech is "no greater than essential" if the "neutral regulation promotes a substantial government interest that would be achieved less effectively absent the regulation."[272] Finally, *O'Brien* is used in both the commercial speech and noncommercial speech arenas.[273]

D. *Speech Constituting Unlawful Behavior*

First Amendment values do not protect "situations where words are an integral part of unlawful conduct and the government uses them to define or characterize unlawful behavior."[274] In *Giboney*, the Supreme Court held that the First Amendment does not prevent the state from "mak[ing] a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed."[275] Furthermore, freedom of speech does not extend to speech used "as an integral part of conduct in violation of a valid criminal statute."[276] For example, illegal conduct carried out by means of speech, like a threat or conspiracy, is not subject to First Amendment protection.[277] Like most generalized laws, prohibitions on these speech acts are subject to rational basis review, under which it will not be invalidated unless it does not rest on a "rational basis."[278] The prohibition on speech constituting unlawful behavior applies equally to commercial speech.[279]

E. *Compelled Speech*

The Supreme Court has recognized a right "to refrain from speaking at all" in the context of political and ideological messages.[280] In *Wooley v. Maynard*, the Court

[270] *See id.* at 376, 381-382 ("In other words, both the governmental interest and the operation of the 1965 Amendment are limited to the noncommunicative aspect of O'Brien's conduct.").

[271] *Id.* at 377.

[272] Rumsfeld v. Forum for Academic & Inst. Rights, Inc., 547 U.S. 47, 67 (2006).

[273] *See* San Francisco Arts & Athletics, Inc., v. U.S. Olympic Comm., 483 U.S. 522, 535-536 (1987); Texas v. Johnson, 491 U.S. 397, 407 (1989).

[274] Evans & Friede, *supra* note 48, at 381.

[275] Giboney v. Empire Storage & Ice Co., 336 U.S. 490, 502 (1949).

[276] *Id.* at 498; *see also* Eugene Volokh, *Speech as Conduct: Generally Applicable Laws, Illegal Courses of Conduct, Situation-Altering Utterances, and the Uncharted Zones,* UCLA School of Law Research Paper No. 04-7, at 31 (May 10, 2004), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_*Id*=545146.

[277] *See* Volokh, *supra* note 276, at 37.

[278] *See, e.g.*, United States v. Lopez, 514 U.S. 549, 615 (1995) (finding rational basis for criminal statute); United States v. Carolene Prods. Co., 304 U.S. 144, 152 (1938); *see also* Evans & Friede, *supra* note 48, at 382.

[279] Pittsburgh Press Co. v. Human Relations Comm'n, 413 U.S. 376, 388 (1973); *see also* Evans & Friede, *supra* note 48, at 381.

[280] Wooley v. Maynard, 430 U.S. 705, 714 (1977).

held that New Hampshire could not require an individual to display the statement "Live Free or Die" on his license plate.[281] The Court reasoned that *Maynard* had a right not to be an ideological "mobile billboard" for the state.[282] Thus, the Court held that *Maynard* had a First Amendment right *not* to speak.[283] Other Supreme Court cases reached this same conclusion.[284] For example, in *Pacific Gas*, the Court held the utility's First Amendment rights were implicated by a requirement that it place a third party's newsletter (with which it disagreed) in its billing envelopes.[285]

A governmental entity may nonetheless permissibly compel noncommercial speech if it meets the standard "strict scrutiny" requirements for speech bans.[286] As noted in *Pacific Gas*, this means the speech requirement is valid if it is a "narrowly tailored means of serving a compelling state interest."[287] Utilizing this test, the Court struck down the statutes in *Pacific Gas* and *Wooley* because they were not narrowly tailored.[288]

The First Amendment also limits the government's ability to compel *commercial* speech, but the test for evaluating compelled commercial speech is less clear.[289] In *Zauderer*, the Court said the speaker's rights are "adequately protected as long as disclosure requirements are *reasonably related* to the State's interest in preventing deception of consumers," though "unjustified or unduly burdensome" affirmative speech requirements would be violative of the First Amendment.[290] Furthermore, *Zauderer* stated that the "least restrictive means" analysis of *Central Hudson* prong four was inapplicable to affirmative disclosure requirements.[291] The Second Circuit in *Amestoy* applied the *Central Hudson* test, however.[292] Moreover, the recent Supreme Court decision in *United Foods* suggested *Central Hudson* would apply in these circumstances.[293] At this point, it is unclear which framework applies to compelled commercial speech.

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[281] *Id*. at 708, 713.

[282] *Id*. at 715.

[283] *Id*.

[284] *See, e.g.*, Miami Herald Publ'g Co. v. Tornillo, 418 U.S. 241, 258 (1974) (invalidating state statute requiring newspapers to allow a "right of reply" to political candidates criticized in their columns); W.V. State Bd. of Ed. v. Barnette, 319 U.S. 624, 636 (1943) (striking down state statute requiring public school students to salute the flag).

[285] Pac. Gas & Elec. Co. v. Pub. Utilities Comm'n of Cal., 475 U.S. 1, 15-16 (1986) (plurality opinion).

[286] *Id.* at 19.

[287] *Id.*

[288] *Id.* at 20-21 (statute cannot be narrowly tailored because it promotes the views of one speaker while burdening another's); *see Wooley*, 430 U.S. at 717 (finding state's interest could not outweigh individual's).

[289] United States v. United Foods, 533 U.S. 405, 410 (2001); Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 651 (1985) ("We recognize that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech."); Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 71 (2d Cir. (1996)); Endejann, *supra* note 196, at 497.

[290] *Zauderer*, 471 U.S. at 651 (emphasis added).

[291] *Id*. at 651 n.14.

[292] *Amestoy*, 92 F.3d at 72-74 (utilizing *Central Hudson* and invalidating Vermont's requirement that dairy products be labeled to disclose the use of recombinant bovine growth hormone); *see also* Endejann, *supra* note 196, at 498; Evans & Friede, *supra* note 48, at 416 (finding *Central Hudson* analysis would apply).

[293] *See United Foods*, 533 U.S. at 410 (discussing the *Central Hudson* approach to analysis of speech restrictions, noting disagreement among the Members of the Court about whether more rigorous review should apply, and noting that, under either *Central Hudson* or more rigorous review, the compelled speech at issue was constitutionally infirm).

F. *Prior Restraints*

A "prior restraint" is an administrative or judicial order that prohibits speech *before* the communication is planned to occur.[294] Traditional First Amendment doctrine erects a "heavy presumption" against the validity of a prior restraint on noncommercial speech and typically, such restraints are upheld only if the restraint system involves judicial supervision and the validity of the restraint is determined "almost immediate[ly]."[295]

The courts have been unclear about whether the presumption against prior restraints will apply to commercial speech. Older Supreme Court dicta suggests it does not. In *Virginia Pharmacy*, the Court stated that the characteristics of commercial speech "may make inapplicable the prohibition against prior restraints."[296] *Central Hudson* even recommended a system of previewing advertisements.[297] In contrast, lower courts have found that the presumption *does* apply.[298]

Central Hudson will likely govern in any case, however: the lower courts employed the test when they found the presumption applicable, and it would also apply if the presumption were inapplicable (because then the restraint would constitute an ordinary commercial speech restriction). In sum, *Central Hudson* controls analysis of prior restraints on commercial speech.

IV. SUMMARY OF FIRST AMENDMENT CASES INVOLVING FDA

This section outlines the recent First Amendment case law concerning FDA.[299] Three major FDA losses—*Western States*, *Pearson*, and *Washington Legal Foundation*—are particularly relevant because they prompted the agency to reconsider its policies and solicit public comment about them.

A. *Western States*

FDAMA provided that manufacturers of compounded drugs were exempt from the new drug, adulteration and misbranding provisions of the FDCA, *provided*

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[294] Alexander v. United States, 509 U.S. 544, 550 (1993).

[295] Bantam Books, Inc., v. Sullivan, 372 U.S. 58, 70 (1963).

[296] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 772 n.24 (1976).

[297] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 571 n.13 (1980).

[298] N.Y. Magazine v. Metro. Transit Authority, 136 F.3d 123, 131-132 (2d Cir. (1998)) (applying *Central Hudson* to find that the transit authority's pre-screening of mass transit ads, a prior restraint, was more extensive than necessary); Desert Outdoor Adver., Inc., v. Outdoor Media Group, Inc., 103 F.3d 814, 819 (9th Cir. (1996)) (applying *Central Hudson*, where prior restraint system pertaining to signage required pre-licensing of certain signs); *In re* Search of Kitty's East, 905 F.2d 1367, 1371 n.4 (10th Cir. (1990)) (noting in dicta that the prior restraint doctrine should be considered applicable to commercial speech); *see also* Comments of Hyman, Phelps, and McNamara, *supra* note 226, at 9 n.19.

[299] Because this article focuses on the First Amendment constraints on FDA and because FDA does not regulate prescriber-identifiable data, it does not discuss in detail the recent decision in *IMS Health v. Ayotte*. In this case, a federal District Court struck down New Hampshire's ban on the use of prescriber-identifiable data under the *Central Hudson* test. 490 F. Supp. 2d 163, 183 (D.N.H. 2007). The court rejected the state's asserted interest in protecting physician privacy, and found its stated interests in promoting the public health and containing drug costs were not "directly advanced" by the law. *Id.* at 179-181. It reasoned that the state had not discharged its prong three burden as to either of these interests because brand drugs are not necessarily more injurious than generics, and generics could in fact be less safe and effective than brand drugs. *Id.* The court also rejected the state's arguments that it needed to prevent inadvisable prescriber decisions as at odds with the Supreme Court's anti-paternalism case law. *Id.* at 179-181 Finally, it found that the state could not meet prong four because it could utilize non-speech based rules—like bans on gifts, Medicaid cost containment measures, and education campaigns—to achieve its goals. *Id.* at 182-183.

they did not advertise or promote the compounding of any particular drug, class of drug or type of drug.[300] *Western States* considered the constitutional validity of this provision.

Because the parties did not dispute that the speech was commercial, true and nonmisleading, the Court focused its analysis on prongs two, three and four of *Central Hudson*.[301] The Court found that the government's interests—preserving the NDA approval process and its attendant protection of the public health and ensuring accessibility of compounded drugs—were "substantial."[302] The Court was less impressed with the government's showing on the third prong. The purpose of the advertising ban was to ensure that pharmacies could not mass manufacture drugs under the guise of compounding, a practice which poses public health risks.[303] The Court agreed that the government needed to distinguish mass manufacturing from legitimate compounding to further its interests, but questioned the propriety of *speech* to make this distinction.[304] After expressing some doubt, the Court assumed that advertising is a "fair proxy" for intent to pursue large-scale manufacturing, as the government asserted.[305] Thus, it found the third prong of *Central Hudson* satisfied.

The Court held that the government could not fulfill prong four, however. First, it did not pursue non-speech-related methods to distinguish large-scale manufacturing from legitimate compounding.[306] Feasible such methods included: 1) banning from pharmacies equipment for large-scale manufacturing; 2) forbidding wholesale sale of compounded drugs; 3) limiting the number, volume or revenue of compounded drugs that could be sold in a given time; or 4) relying on other aspects of the FDAMA compounding provisions, which required prescriptions for compounded products and capped the amount of revenue a pharmacy could receive from out-of-state compounding sales.[307] Second, the Court held that the government offered no justification for its failure to pursue these alternative means of regulation.[308]

B. *Pearson v. Shalala*

In *Pearson*, dietary supplement manufacturers challenged FDA's rejection of their proposed health claims on First Amendment grounds.[309] These manufacturers sought approval of claims stating that: 1) relationships "may" exist between the consumption of antioxidants, fiber and omega-3 fatty acids, and a reduction of risk for, respectively, some types of cancer, colon cancer and heart disease; and 2) 0.8 mg of folic acid "is more effective in reducing the risk of neural tube defects than

[300] FDAMA, Pub. L. No. 105-115, § 127(a), (c), 111 Stat. 2296, 2328 (1997) (codified at 21 U.S.C. § 353a) (emphasis added).

[301] *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 367 (2002).

[302] *Id.* at 368-370. The majority rejected the dissent's assertion that the government had a "substantial" interest in prohibiting the sale of compounded products to patients who do not need of them. *Id.* at 373-375. The Court found that this interest was grounded in a paternalistic assumption that citizens would respond irrationally to advertising, in contravention of First Amendment principles announced in *Virginia Pharmacy*. *Id.* at 374-375. The Court also expressed skepticism about the dissent's "questionable" assumption that doctors would respond to patient demands by over-prescribing. *Id.* at 374.

[303] *Id.* at 362-365.

[304] *See id.* at 370.

[305] *See id.* at 370-371.

[306] *Id.* at 371.

[307] *Id.*

[308] *Id.* at 373.

[309] Pearson v. Shalala, 164 F.3d 650, 651-652 (D.C. Cir. (1999)).

a lower amount in foods in common form."[310] FDA rejected the proposed claims as not supported by significant scientific evidence, because the studies supporting the first three claims involved foods (not dietary supplements) and the evidence for the folic acid claim did not show that dietary supplements were superior folic acid sources to food.[311] FDA would not allow any "corrective disclaimer[s]" in conjunction with the claims but instead outright banned these claims.[312]

In assessing the speech restriction, the D.C. Circuit applied *Central Hudson* because the parties agreed the commercial speech doctrine was applicable. The government first argued that the proposed claims were inherently misleading because they were unsupported by significant scientific agreement. The court construed this argument to contend that such claims "make it virtually impossible for [consumers] to exercise any judgment *at the point of sale*," as though they were offered the supplement "while hypnotized."[313] The court rejected this argument as "almost frivolous" and premised on impermissible paternalistic assumptions.[314]

The government also argued that the claims were potentially misleading, and thus, it did not need to consider a disclaimer policy for them. Instead, the court found that full *Central Hudson* analysis was appropriate.[315] Under this analysis, the court found that the second prong was satisfied because the government had substantial interests in protecting the public health and guarding against deceptive market practices.[316] The government fulfilled the third prong as to the latter of these interests only. For the former, it did not provide evidence but instead contended that "common sense" supported its position, suggesting that consumers did not have the time or wherewithal to analyze claims.[317] The court rejected this argument, finding that it was paternalistic and did not directly advance public health.[318] The government fulfilled the third prong for the consumer fraud interest, because some health claims would invariably mislead the public and a high standard requiring FDA approval would reduce the amount of fraud.[319]

The government's refusal to adopt a disclaimer policy caused it to fail prong four.[320] The court found that the fourth prong could not be satisfied "when the government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness … ."[321] It stated that the government should instead adopt disclaimers indicating the level of evidence supporting the claims, describing side effects, and explaining that the claims were not FDA-approved.[322] It distinguished *Friedman v. Rogers* because the claims conveyed factual information, while the trade names in *Rogers* had meaning only through association.[323] On remand, the court directed the FDA to formulate proper

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[310] *Id.* at 652.
[311] *Id.* at 653-654.
[312] *Id.*
[313] *Id.* at 655.
[314] *Id.*
[315] *Id.*
[316] *Id.* at 655-656.
[317] *Id.* at 656.
[318] *Id.*
[319] *Id.*
[320] *Id.* at 657.
[321] *Id.* at 658. The court noted in passing that the dietary supplement manufacturers had no other methods of communicating the health claims that would be as effective as putting them on the label. *Id.* at 658 n.7.
[322] *Id.* at 658-659.
[323] *Id.* at 657.

disclaimers.[324] The court did, however, find that disclaimers would be inappropriate and a total ban permissible if "credible evidence" did not support the claim or if the government "demonstrate[d] *with empirical evidence*" that disclaimers would not convey the intended message and instead lead to consumer confusion.[325]

C. *Washington Legal Foundation*

The *Washington Legal Foundation* case included two separate district court opinions considering FDA policy on off-label speech.[326] The first considered the constitutional validity of FDA's guidance on industry-supported scientific and educational activities and advertising and promotion guidances, while the second reviewed FDAMA's off-label provision.[327]

In the first decision, the D.C. federal district court found the agency's off-label policies violative of the First Amendment. First, the court was highly skeptical of the agency's position that off-label speech constituted "conduct" rather than "speech."[328] According to the court, off-label speech can only be harmful to the extent physicians listen to it, hence suggesting the impact of the promotion depends on its content.[329] Therefore, the court found that off-label speech is "only 'conduct' to the extent that moving one's lips is 'conduct.'"[330]

Similarly, the court rejected FDA's argument that the First Amendment was inapplicable because the speech "occurs in an area of extensive government regulation."[331] The cases on which FDA relied, which dealt with the propriety of disclosure obligations in the securities context, were of doubtful validity in light of subsequent Supreme Court jurisprudence that applied *Central Hudson* to many highly regulated industries.[332] Thus, the court concluded that the Guidance Documents were subject to First Amendment scrutiny.

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[324] *Id.* at 659. After remand, FDA continued to refuse to allow the folate claims, accompanied by disclaimers, on the rationale that they were "inherently misleading," and instead proposed specific language for four alternative folate claims. Pearson v. Shalala, 130 F. Supp. 2d 105, 108, 111 (D.D.C. (2001)). The court granted a preliminary injunction enjoining FDA action that would prevent plaintiff's folate claims. *Id.* at 112. According to the court, FDA "at best, misunderstood, and at worst, deliberately ignored" the Court of Appeals decision. *Id.* Because the scientific evidence did not weigh against plaintiff's proposed claim, the claim was not inherently misleading and could be subject to disclaimers. *Id.* at 115. The court found that the "absence of significant affirmative evidence" supporting plaintiff's claim is not negative evidence against it and thus a ban was not permitted. *Id.* Moreover, FDA did not demonstrate that plaintiff's proposed disclaimers would "bewilder" consumers so as to justify a ban under the Court of Appeals opinion. *Id.* at 118. The case was therefore remanded to FDA to draft disclaimers that would accompany plaintiff's claims. *Id.* at 120. FDA's subsequent motion for reconsideration was denied in an opinion that chided FDA for its continuing failure to comply with the D.C. Circuit opinion. Pearson v. Thompson, 141 F. Supp. 2d 105, 112 (D.D.C. (2001)).

[325] Pearson, 164 F.3d at 659-660 (emphasis added). A subsequent case developed the "credible evidence" standard to mean that FDA could only ban claims where no evidence supported the claims, where only one or two old tests supported them, or where FDA demonstrated with empirical evidence that disclaimers would be confusing. Whitaker v. Thompson, 248 F. Supp. 2d 1, 9-10 (D.D.C. (2002)); *see also* Pearson v. Shalala, 130 F. Supp. 2d 105, 114-15 (D.D.C. (2001)).

[326] Washington Legal Found. v. Henney, 56 F. Supp. 2d 81 (D.D.C. (1999)); Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. (1998)).

[327] *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d at 54; *Washington Legal Found. v. Henney*, 56 F. Supp. 2d at 83.

[328] *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d at 59.

[329] *See id.*

[330] *Id.*

[331] *Id.* at 60.

[332] *Id.* FDA relied heavily on *Dun and Bradstreet, Inc., v. Greenmoss Builders, Inc.*, 472 U.S. 749, 759 n.5 (1985), which found that some speech could be regulated without violating the constitution. *Western States* confirms that typical *Central Hudson* analysis applies to FDA's regulations. *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 368 (2002) (applying *Central Hudson* to FDA).

The court next found the speech was commercial.[333] The court reasoned that the speech proposed a commercial transaction because off-label speech "suggests that a physician should prescribe—and a consumer will therefore purchase—the subject drug."[334] It also applied *Bolger* to bolster this conclusion.[335] The court found the off-label speech constituted an advertisement for purposes of the *Bolger* test. In reaching this conclusion, the court utilized a broad definition of "advertisement" that included essentially all materials that "call public attention" to the product … so as to arouse a desire to buy."[336] It found that the off-label speech referred to a specific product, because the manufacturers only seek to distribute reprints of articles that specifically discuss their products and do not provide free journal subscriptions or other generalized materials.[337] Finally, the court concluded that the last part of the *Bolger* test was fulfilled, because manufacturers had an economic motivation for the speech. Indeed, the manufacturers distributed the materials in hopes of increasing sales.[338] Therefore, the speech was commercial, and *Central Hudson* governed.

FDA argued that the speech itself was illegal and therefore violated prong one. The court rejected this contention. According to the court, the first prong permits speech bans when underlying activity that the speech promotes is illegal, but in this case, the underlying activity—physician prescription of an off-label use—was concededly legal.[339] The court also rebuffed FDA's argument that safety and efficacy claims lacking its approval are all inherently misleading, noting that such a formulation was reflective of FDA "exaggerat[ing] its overall place in the universe."[340] The speech was not inherently misleading because speech restrictions short of a ban would cure the misleading qualities. For example, FDA could mandate disclaimers concerning the manufacturer's financial interest and lack of FDA approval for the use; a peer-review requirement for journal articles; an independent publisher requirement for reference texts; an "independent program provider" requirement for continuing medical education (CME) programs; and case-by-case enforcement of the "false and misleading" prohibition.[341]

FDA asserted that its off-label policy provided incentives for obtaining supplemental NDA approval, and ensured that physicians received accurate information. The court found the first interest substantial—based on Congress' finding that a premarket approval system was warranted due to past abuses—but dismissed the second as premised on a paternalistic notion that physicians, a sophisticated audi-

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[333] *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d at 64-65.

[334] *Id.* at 64.

[335] The court applied *Bolger* and the commercial transaction framework as through they are interdependent grounds. As discussed above, this approach is in contrast to the one suggested by Supreme Court doctrine, which seems to imply that proposal of a commercial transaction and fulfillment of the *Bolger* factors are alternative grounds for a finding that the speech is commercial. Again, lively debate exists on this issue, and Supreme Court doctrine is not entirely clear.

[336] *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d at 64.

[337] *Id.*

[338] *Id.*

[339] *Id.* at 66. The court noted that the government's argument was "tautological" since it was based on the logic that Congress made the speech illegal, and hence the speech concerned an unlawful activity. *Id.*

[340] *Id.* at 67. The court also concluded that the policy of allowing off-label materials to be distributed at physician request was inconsistent with FDA's contention that such materials were inherently misleading. *See id.* According to the court, "the exact same [enduring material] cannot be inherently conducive to deception and coercion when it is sent unsolicited, yet of significant clinical value when mailed pursuant to a request." *Id.*

[341] *Id.* at 68-69.

ence, cannot evaluate the validity of promotional materials.[342] The court also decided that the off-label policy satisfied prong three, because it nullified the disincentives to pursue the supplement approval process (such as the expense and delay of the process) mandating that manufacturers go on-label.[343]

The policy failed prong four, however. Disclosures constituted a less restrictive alternative to banning off-label speech. They would alert physicians that the product had not been approved for the new use and would be subject to "the full battery of FDA enforcement options" if incomplete or misleading.[344] Moreover, a disclaimer system would preserve incentives to go on-label because the manufacturers would still be unable to draft and distribute their own off-label materials, conduct on-label CME without an independent program provider, or conduct DTC advertising for the use.[345] Further, an FDA-approved product would remain more attractive to physicians for purposes of malpractice liability.[346]

The court issued an order enjoining FDA from restricting: 1) manufacturer selection of CME content and speakers, and 2) manufacturer distribution of reprints from a peer-reviewed journal or generally available reference text that discuss off-label uses without mentioning the FDA approved use.[347] The injunction noted that FDA could require disclaimers and aggressively enforce the ban on false and misleading information.

In the second decision, the court invalidated FDAMA section 401 as perpetuating the problematic policies it rejected in the first decision.[348] Citing heavily to the first opinion, the court again found the speech commercial, prong one unviolated, and the government's asserted interest in preserving the supplemental NDA system substantial.[349] The FDAMA requirement that the manufacturer file a supplemental NDA within a certain timeframe as a pre-condition to off-label reprint distribution directly advanced this interest, but the other components of the FDAMA provision did not.[350] Prong four was again unsatisfied because the supplemental NDA requirement amounted to "a kind of constitutional blackmail": it obligates the manufacturer to comply with the statute or sacrifice their rights.[351] Viable, less restrictive alternatives to the speech ban existed, such as monetary penalties for failure to file supplemental NDAs, more aggressive enforcement, bans on off-label prescribing or the derivation of profits from off-label prescriptions.[352] Thus, the court held that the FDAMA provision was unconstitutional.[353]

D. *Amestoy*

In *Amestoy*, the Second Circuit invalidated, based on prong two of the *Central Hudson* test, a Vermont statute requiring milk label disclosures concerning the use

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[342] *Id.* at 69-71.
[343] *Id.* at 71.
[344] *Id.* at 73.
[345] *Id.*
[346] *Id.*
[347] *Id.* at 74.
[348] Washington Legal Found. v. Henney, 56 F. Supp. 2d 81, 82-84 (D.D.C. (1999)).
[349] *Id.* at 85.
[350] *Id.* at 86-87.
[351] *Id.* at 87.
[352] *Id.*
[353] *Id.* at 87-88. *Henney* was subsequently reviewed by the D.C. Circuit, but by then, FDA had modified its strategy and argued that FDAMA merely created a "safe harbor" and hence did not ban any speech. The D.C. Circuit thus vacated the *Henney* judgment because of the absence of a "constitutional controversy," but noted that "we certainly do not criticize the reasoning or conclusions of the district court." Washington Legal Found. v. Henney, 202 F.3d 331, 337 n.7 (D.C. Cir. (2000)).

of synthetic growth hormones in cows.[354] FDA had found the use of the hormone has no effect on the milk in terms of safety or composition.[355] According to the court, the Vermont statute was not justified on the basis of any health reason or to avoid the economic exploitation of the purchaser, but instead was meant to satisfy consumer curiosity/the public's "right to know."[356] Therefore, the court found this statute did not address real harms as required by *Edenfield*.[357] It noted that, were consumer interest in information sufficient to warrant compelled disclosure, "there is no end to the information that states could require manufacturers to disclose about their production methods."[358]

E. *Nutritional Health Alliance*

In this case, plaintiffs brought a facial challenge to the pre-approval requirement for dietary supplement health claims.[359] The court considered whether the suit was ripe for review.[360] The court reasoned that the main injury to plaintiffs from denying review would be to subject them to the prior restraint of utilizing the FDA health claim petition process.[361] The court found that prior restraint analysis "does play a role" in evaluating the constitutional propriety of a commercial speech restriction, but that FDA's statutory 540-day deadline for ruling on a health claim was acceptable under *Central Hudson* for several reasons.[362] Specifically, the court found the restriction was valid under the fourth prong because some form of pre-approval is necessary to protect the public health; the statute required the agency to develop a record; the 540-day deadline was "limited but reasonable"; and the "significant scientific agreement" standard was definite enough to ensure that the agency did not have unfettered discretion (a typical problem associated with prior restraints).[363]

F. *Whitaker*

In *Whitaker*, the D.C. Circuit considered whether FDA's health claim rules—which classified products bearing unapproved health claims as drugs—violated the First Amendment.[364] In that case, plaintiffs sought to claim that saw palmetto extract could mitigate symptoms of benign prostatic hyperplasia, but FDA rejected it as an impermissible disease claim.[365] The court rejected plaintiffs' First Amendment

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[354] Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 71-73 (2d Cir. (1996)).

[355] *Id.* at 73.

[356] *Id.*

[357] *Id.*

[358] *Id.* at 74.

[359] Nutritional Health Alliance v. Shalala, 144 F.3d 220, 222 (2d Cir. (1998)). A previous, related case considered a challenge to FDA's lack of a deadline for review of health claims. Nutritional Health Alliance v. Shalala, 953 F. Supp. 526, 532 (S.D.N.Y. (1997)). The court held that FDA needed to establish a "reasonable deadline" for health claim review. *Id.*

[360] Nutritional Health Alliance v. Shalala, 144 F.3d at 225.

[361] *Id.* at 226 n.11, 227.

[362] *Id.* at 227-228. The court "[saw] no reason why the requirement of procedural safeguards in [prior restraint cases] should be relaxed whether the speech is commercial or not." *Id.* at 226. It found *Central Hudson* "supports continuing to require procedural safeguards for prior restraints even where commercial speech is involved." *Id.* at 228. The court reasoned that prong four analysis demands it to examine whether the speech restriction is also a prior restraint. *Id.*

[363] *Id.* Another case considered the same facial challenge to the pre-approval requirement for dietary supplement health claims, but found the plaintiffs lacked standing. Nat'l Council for Improved Health v. Shalala, 122 F.3d 878, 880, 884 (10th Cir. (1997)).

[364] Whitaker v. Thompson, 353 F.3d 947, 953 (D.C. Cir. (2004)).

[365] *Id.* at 948-949.

challenge. It held that the statute simply used manufacturer speech as evidence of intent to market a drug.[366] According to the court, *Wisconsin v. Mitchell* shows that the First Amendment allows "the evidentiary use of speech to establish the elements of a crime or to *prove motive or intent*."[367] Hence, the court concluded that FDA could use plaintiffs' claims as evidence that the product was a drug. In other words, the court essentially found *Central Hudson* inapplicable to the classification of products under the FDCA.

V. HOW THE FIRST AMENDMENT NOW AFFECTS FDA'S DAILY BUSINESS

This section assesses the constitutional propriety of FDA's statutes, regulations and policies pertaining to: 1) the evidentiary use of speech; 2) the standard for evaluating whether a statement is misleading; 3) labeling; 4) food and dietary supplement claims; 5) advertising; 6) off-label speech; and 7) speech about unapproved drugs. In each section, this paper determines the type of speech that is regulated and evaluates the constitutionality of the restrictions using the applicable framework. Where appropriate, it suggests how FDA might modify its policies to conform to the First Amendment.

A. *Evidentiary Use of Speech for Product Classification*

Scholars deeply disagree about what level of First Amendment analysis is proper for the statutory provisions authorizing the use of manufacturer speech to determine a product's intended use. As noted, the *Whitaker* court found the First Amendment allows "evidentiary use of speech … to prove motive or intent," citing to Supreme Court precedent in *Mitchell*.[368] Evans and Friede reason that such speech is incidentally regulated as part of the direct regulation of manufacturer *conduct*, and therefore is only subject to "rational basis review," a lenient standard.[369] FDA has adopted similar reasoning in an analogous context.[370] In contrast, scholars Blackwell and Beck conclude that, in the wake of *Western States*, use of speech as a trigger for regulatory requirements must survive full First Amendment review.[371]

A court would likely find that the *Whitaker* approach is correct. It would likely reason that *Western States* is not properly analogous to this use of speech as follows. In *Western States*, the statute required pharmacists to abstain from advertising to qualify for the compounding exemption. It used advertising as a "fair proxy for actual or intended large-scale manufacturing," in all cases and made no fact-based inferences as to individual manufacturer intent.[372] In other words, the statute in *Western States* did not use speech to ascertain intent but instead *presumed* speech signified certain intent, without any context-based analysis as to individual speech.

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[366] *Id.* at 953.

[367] *Id.* (quoting Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993)).

[368] *Id.* (citing *Mitchell*, 508 U.S. at 489 (omit)); *see also* Evans & Friede, *supra* note 48, at 389-391; Comments of Freedom to Advertise Coal. in response to Request for Comment, Docket No. 02N-0209, Comment C73, at 8 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091802/02n-0209-c000073-01-vol18.pdf; Comments of Nat'l Ctr. For Tobacco-Free Kids in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C44, at 4-6 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d30.pdf; Comments of Pfizer, *supra* note 194, at 67-69.

[369] Evans & Friede, *supra* note 48, at 382, 389-391.

[370] *See* Regulations for Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1,000, 1,038 (Jan. 6, 2000).

[371] Blackwell & Beck, *supra* note 175, at 445-446.

[372] Thompson v. W. States Med. Ctr., 535 U.S. 357, 370-371 (2002).

It therefore required abstention from speech to obtain regulatory benefits, regardless of the manufacturer's individual intent. When speech is utilized for evidentiary purposes under the FDCA, it is used to determine individual manufacturer intent, which only *then* triggers product classification and attendant regulatory requirements.[373] The FDCA provision does not, as in *Western States*, erect an irrebuttable presumption of intent that in practice requires all manufacturers, regardless of actual intent, to cease their advertising efforts if they wish to utilize regulatory exemptions. Because *Mitchell* explicitly allows the evidentiary use of speech to prove individual intent, a court would probably conclude that the FDCA regime is constitutionally permissible.

Furthermore, even if the evidentiary use of speech were to be classified as a speech restriction as Blackwell and Beck suggest, it is likely that courts would find it passes *Central Hudson*.[374] The underlying speech concerns the use of various FDA-regulated products, which is not unlawful activity, and the speech is not generally false or misleading.[375] The speech regulation furthers a substantial interest: FDA's interest in ensuring that products are regulated for their proper use so they will be used safely and effectively.[376] A court is also likely to find that the restriction also is the most direct way to advance this interest, because it allows classification as a drug to take place prior to use so that safety and efficacy are ensured before public use.[377] Finally, judges will probably conclude that there are no less restrictive alternatives. The intended use is mentioned in the labeling and other manufacturer speech and therefore, consumers are likely to put the products to these uses.[378] Though Congress could use *actual* use as a trigger for regulation as a drug, this would require putting the product on the market first and then seeing how it worked, which would expose the public at large to risks and therefore would not effectively promote the government's interest in ensuring safe and effective drugs and devices.[379] Thus, the evidentiary use of speech is probably the least restrictive possible alternative.

In sum, evidentiary use of speech to determine manufacturer intent would probably be viewed as constitutionally permissible under *Mitchell*. Even if this use qualifies as a speech restriction, courts will probably find it passes *Central Hudson* muster.

B. *"Reasonable Person" or "Ignorant, Unthinking and Credulous"*

Commentators disagree as to the appropriate standard for audience wherewithal in the context of determining whether speech is misleading. Some parties argue that speech should be evaluated based on the perspective of a "reasonable person" while others believe that the perspective of "the ignorant, the unthinking, and the credulous" should be used.[380] FDA took the latter approach from 1906-2002, but

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[373] *Whitaker*, 353 F.3d at 953.

[374] Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. at 1,038.

[375] FDA suggests the substantial interest is as to regulating the *unapproved* use of drugs. *Id.* The speech is used as evidence of intent for all drugs, including those that are generally recognized as safe and effective and those that are approved, however, so the underlying activity cannot be said to be generally illegal. Additionally, courts will not likely find that the underlying activity is illegal even with respect to off-label speech and speech about unapproved drugs, as discussed below.

[376] Comments of Pfizer, *supra* note 194, at 70.

[377] *See id.*

[378] *See* Comments of Freedom to Advertise Coal., *supra* note 368, at 35.

[379] Comments of Pfizer, *supra* note 194, at 70.

[380] Comments of Grocery Mfrs. of Am., Comment C21, *supra* note 105, at 5 (collecting cases in which FDA argued for this standard).

recently modified its position to adopt the "reasonable person" standard, at least in the food labeling context.[381]

The Supreme Court has suggested that capabilities of the intended audience should be evaluated based on the facts of the case, rejecting bans with respect to sophisticated audiences but permitting them with respect to vulnerable accident victims.[382] Where the general public is concerned, however, the Court has rejected paternalist rationales and found that individuals "will perceive their own best interests."[383] Consequently, usage of the "reasonable person" standard as a background presumption appears proper, but specific circumstances may justify deviation from this standard.

FDA's recent decision to switch from the default presumption of an ignorant, unthinking, and credulous consumer to a "reasonable consumer" for the general public is appropriate. FDA also must conduct case-by-case analysis to determine when departure from this presumption is required.[384] If the audience is particularly sophisticated, the use of a standard higher than that of a "reasonable person," such as that of a reasonably skilled physician, is proper.[385] Furthermore, the standard may need to be ramped down if the audience is particularly vulnerable.

It does not seem likely, however, that the "ignorant, unthinking, and credulous" standard will be appropriate. First, this standard seems overly paternalistic as it assumes a permanently low level of skill overall rather than merely a lack of information with regard to certain technical information (like prescription drugs), or a temporary stressful and vulnerable period. A background presumption of ignorance is inconsistent with the spirit of *Virginia Pharmacy* and its progeny. Second, little speech could pass this standard, because "[s]ome consumers will misunderstand even the clearest and most unambiguous statement," and hence this is a not a fair or workable standard to determine whether a communication is misleading.[386] In sum, under governing doctrine, the "reasonable person" standard is the appropriate background presumption, with the caveat that individual facts of the case may raise or lower this standard.

C. *Labels and Labeling*

Because the labeling requirements are similar across product categories, five different types of general labeling restrictions will be analyzed: 1) the definition of "labeling"; 2) affirmative labeling requirements; 3) negative labeling prohibitions; 4) formatting requirements and 5) specific language requirements.[387]

1. *"Labeling"*

The issue is whether the total prohibition of "labeling" materials that do not adhere to the package insert requirements is constitutional. Numerous comments

[381] FDA, Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed. Reg. 78,002, 78,004 (Dec. 20, 2002).

[382] *See* Edenfield v. Fane, 507 U.S. 761, 775-776 (1993) (contrasting the sophistication of a CPA's clients from that of the vulnerable accident victims in *Ohralik*).

[383] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976).

[384] *See* Comments of the Ctr. for Constitutional Rights, *supra* note 220, at 6-8.

[385] *See* Comments of Hyman, Phelps, and McNamara, *supra* note 226, at 23.

[386] Comments of Grocery Mfrs. of Am., Comment C21, *supra* note 105, at 5.

[387] Evans and Friede utilize a similar framework. Evans & Friede, *supra* note 48, at 391-401; *see also* Comments of Am. Frozen Food Inst. in response to Request for Comment, Docket No. 02N-0209, Comment C16, at 3 (Aug. 5, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/080602/8001de48.pdf.

argued that FDA's interpretation of "labeling" is far too expansive and goes beyond the scope of *Kordel*, because it includes materials that do not accompany the product or serve the function of a label.[388] In particular, commentators object to inclusion of press releases, calendars, sound recordings, books, brochures, handouts, etc., within the definition of labeling.[389] They contend that FDA places a palpable burden on the expression of speech in these media, and requires "more disclosure than necessary" by requiring these materials to comply with its extensive labeling requirements.[390] The commentators disagree on how to resolve this problem, however. Some argue that these materials should be regulated as advertising, while others suggest they are noncommercial speech to the extent they discuss clinical trials.[391] This section does not consider the regulatory issue of whether these materials should properly be considered "labeling." Instead, it evaluates the constitutionality of treating them as such and applying the full range of "labeling" requirements to them.

a. Applicable Framework

Courts are likely to find that the books, calendars and other materials are "speech." FDA might argue, that this dissemination of this information is "conduct," not "speech." The materials at issue are, however, regulated due to their content and their primary effect on the listener, suggesting they are speech.[392] Thus, as PhRMA notes, these materials "are of course a form of speech."[393]

A more difficult issue is what type of speech is involved. Materials like press releases, books, and calendars do not propose a commercial transaction. Taking *Washington Legal Foundation* as precedent, courts will likely apply the *Bolger* framework.[394] A manufacturer has economic motivations behind the distribution of books, calendars, etc., as these are disseminated to bring attention to the product and increase sales of the product.[395] Furthermore, the materials at issue are likely to refer to a specific product rather than drugs in general, as manufacturers are unlikely to disseminate general materials on pharmaceutical products that do not mention their own products.[396] The most difficult issue is whether these materials are "advertisements." The *Friedman* court employed a broad definition of "advertisement," sweeping in essentially all materials that attract public attention to the

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[388] *E.g.,* Comments of Biotechnology Indus. Org. in response to Request for Comment, Docket No. 02N-0209, Comment C66, at 7-8 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091802/80027f45.pdf; Comments of Freedom to Advertise Coal., *supra* note 368, at 35; Comments of Nat'l Venture Capital Ass'n, *supra* note 226, at 13-14; Comments of Pfizer, *supra* note 194, at 71-74; Comments of PhRMA, *supra* note 191, at 34-38. Most of these commentators were satisfied with the application of these regulations to informational materials that actually accompany the product as it arrives in the consumer's hands, and therefore serve as the "consumers' [or physicians'] last resource" as to information about the product. Comments of Freedom to Advertise Coal., *supra*, at 35; *accord* Evans & Friede, *supra* note 48, at 392 (referring to the "operative labeling" as the "only appropriate labeling upon which healthcare professionals should rely").

[389] Evans & Friede, *supra* note 48, at 392; Comments of Freedom to Advertise Coal., *supra* note 368, at 35.

[390] Evans & Friede, *supra* note 48, at 392; Comments of Freedom to Advertise Coal., *supra* note 368, at 35.

[391] Comments of Pfizer, *supra* note 194, at 72-73; Comments of PhRMA, *supra* note 191, at 36.

[392] *See* Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51, 59 (D.D.C. (1998)); *cf.* Evans & Friede, *supra* note 48, at 393-394.

[393] Comments of PhRMA, *supra* note 191, at 35.

[394] *See supra* note 199.

[395] *See Washington Legal Found.*, 13 F. Supp. 2d at 62.

[396] *See id.*

product.[397] Under this definition, press releases, books, calendars, etc., would be "advertisements." Critics have argued that this definition is too broad.[398] Courts are likely to use it, however, because it is in accord with major dictionaries.[399] As such, courts will probably conclude that press releases, calendars, and other such materials that refer to a product so as to attract public attention are commercial speech. This conclusion accords with a general trend among the courts to consider manufacturer speech under the commercial speech framework.[400] Furthermore, it is consistent with the facts of *Bolger*, where informational pamphlets about condoms were found to be commercial speech.[401]

In some circumstances, however, these materials may constitute noncommercial speech. For example, as Judge Lamberth suggested, if the manufacturer sought to distribute free journal subscriptions or other materials that were not solely related to its own products, this speech would be noncommercial.[402] Under *Bolger*, the speech is noncommercial if it: 1) is not economically motivated; 2) does not reference a specific type of product; or 3) does not attempt to call attention to such products.[403] In these circumstances, the speech should be considered noncommercial. Finally, when the two types of speech are blended, an open question exists as to the proper level of scrutiny. *Fox* suggested commercial speech analysis would apply, and *Discovery Network* later provided that a fact-specific inquiry was appropriate.[404] After *Nike*, the appropriate level of scrutiny is unclear.

b. The Framework Applied

"Labeling" materials generally do not pertain to an illegal activity.[405] Moreover, such speech could not be "deemed false or inherently misleading as a general rule."[406] Courts likely will conclude that the government has substantial interests in 1) ensuring that the audience has adequate information, including negative information,

[397] *See id.*

[398] Gilman, *supra* note 182, at 468 ("The [*Friedman*] reading of 'advertisement,' if unproblematic qua fact-finding, is at best as [sic] strained judicial construction"). Gilman argues that using a definition of "advertisement" as speech calling attention to a particular product adds nothing to the other two *Bolger* factors. *Id.; see also* Kamp et al., *supra* note 5, at 563-564.

[399] *See, e.g.,* American Heritage Dictionary, http://dictionary.reference.com/search?q=advertisement (defining "advertisement" as "[a] notice, such as a poster or a paid announcement in the print, broadcast, or electronic media, designed to attract public attention or patronage"); Cambridge Advanced Learner's Dictionary, http://dictionary.cambridge.org/define.asp?key=1230&dict=CALD (defining advertisement as "a picture, short film, song, etc. which tries to persuade people to buy a product or service"); Merriam-Webster's Online Dictionary, http://www.m-w.com/dictionary/advertising (defining advertising as "to call public attention to especially by emphasizing desirable qualities so as to arouse a desire to buy or patronize"); MSN Encarta Dictionary, http://encarta.msn.com/dictionary_/advertise.html (defining "advertise" as "to publicize the qualities of a product, service, business, or event in order to encourage people to buy or use it").

[400] Samp, *supra* note 197, at 314; *see also* United States v. General Nutrition, 638 F. Supp. 556, 562 (W.D.N.Y. (1986)) ("To the extent that the "speech" concerning the product is independent of its marketing, this Court is unaware of any effort, desire or right of the government to challenge it.").

[401] Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51, 62 (D.D.C. (1998)); Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 67 n.13, 68 (1983).

[402] *Washington Legal Found.*, 13 F. Supp. 2d at 64.

[403] *See Bolger*, 463 U.S. at 67.

[404] *Compare* Bd. of Trustees of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 474 (1989) (noting that the *Riley* rule was inappropriate on the facts of the case) *with* City of Cincinnati v. Discovery Network, 507 U.S. 410, 422-423 (1993).

[405] *See Washington Legal Found.*, 13 F. Supp. 2d at 66.

[406] Comments of Pfizer, *supra* note 194, at 97; *see also* Comments of Nat'l Venture Capital Ass'n, *supra* note 226, at 13 ("FDA must be able to point to concrete evidence that particular press releases are misleading or [false].").

to assess the value of the drug; and 2) assuring that adequate incentives exist for premarket approval process of labeling for drugs, biologics and some devices.[407] The *Washington Legal Foundation* court found the former interest insubstantial in the context of off-label speech, contending that it was borne out of the paternalistic assumption that a sophisticated audience could not assess the validity of promotional materials. Other courts are likely to find this logic flawed, however, in light of Supreme Court case law. Specifically, the Supreme Court's aversion to paternalism is predicated on the notion that people "will perceive their own best interests *if only they are well enough informed*."[408] As such, a government interest that seeks to provide *more* information to people to ensure they have a sufficiently complete body of information on which to base a conclusion is consistent with Supreme Court precedent.[409] Furthermore, unlike in *Washington Legal Foundation*, the audience for press releases, calendars, and other materials at issue may include consumers as well as healthcare professionals. In short, courts likely will find that the government has two "substantial interests."

Courts will further likely find that the inclusion of press releases, books, calendars and other materials that do not accompany the product as "labeling," with the attendant regulatory consequences, will directly advance the government interests.[410] To make this showing, FDA need offer evidence that its restrictions both provide the audience with sufficient information to evaluate the product, and incentives to undergo the relevant approval processes, and that the restrictions are not impermissibly over or under-inclusive as in *Rubin*.

FDA could not fulfill prong four, however.[411] As PhRMA suggests, disclaimers could be required to disclose the level of evidentiary support for the information and applicable negative information without subjecting the material to the full battery of requirements that the package insert must fulfill, like neutral tone.[412] Furthermore, product approval would still be valuable because it is necessary for legal sales of the drug itself, product liability and insurance protections.[413] Requiring the full product labeling for something like a calendar is unduly burdensome, even for an affirmative requirement.

One older FDA preamble argued that applying "labeling" rules to books does not violate the First Amendment,[414] but this relied on the contention that the First Amendment does not restrict regulations in highly regulated areas like securities, which the Court rejected implicitly in *Western States*.[415] Subsequent preambles have not considered this issue explicitly.[416] The third party literature exemption in

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[407] Comments of PhRMA, *supra* note 191, at 37.

[408] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976) (emphasis added); *see also* 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 497 (1996)(plurality opinion) (discussing that the underlying rationale for commercial speech—dissemination of useful information to consumers—also supports ensuring that the information is accurate and understandable).

[409] *See Va. Pharmacy*, 425 U.S. at 770.

[410] *See Washington Legal Found.*, 13 F. Supp. 2d at 71-72.

[411] Comments of Nat'l Venture Capital Ass'n, *supra* note 226, at 13-14; Comments of PhRMA, *supra* note 191, at 37.

[412] Comments of PhRMA, *supra* note 191, at 37.

[413] *Id.*

[414] Notice Concerning Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074, 64,077 (Dec. 3, 1997).

[415] *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 368 (2002) (applying *Central Hudson* to FDA).

[416] *E.g.,* Consumer-Directed Promotion of Regulated Medical Products; Public Hearing, 70 Fed. Reg. 54,054, 54,055 (Sept. 13, 2005) (discussing broad interpretation of "labeling" but offering no First Amendment analysis of this interpretation).

the dietary supplement context is a step in the right direction but does not go far enough to comport with courts' likely interpretations of the First Amendment. It covers only materials with a "balanced" view and references to a specific brand or manufacturer do not fall into this exemption. The agency should utilize the same approach as in the qualified claims guidance to mandate simple disclaimers for use in press releases, books, etc., without causing undue burden.

To the extent noncommercial speech is involved, the regulations will be subject to strict scrutiny.[417] This test is exacting, and the vast majority of regulations that are evaluated under this standard fail.[418] Where the government *intends* content-based suppression of noncommercial speech, as here, "the general rule is that the right of expression prevails, even where no less restrictive alternative exists."[419] As such, these regulations are likely unconstitutional.

2. *Prohibitions*

This section considers the constitutional propriety of prohibitions on information in the product label or in labeling. It examines whether FDA can outlaw false or misleading information in labeling. It also considers whether FDA can ban factual statements about the product and opinions or performance claims in the labeling.

a. Applicable Framework

As discussed above, courts are likely to apply *Bolger* and find that labeling is commercial speech. Courts will probably find that labeling is economically motivated, presented with the product at the point of purchase, and calls attention to the product.

b. The Framework Applied: Prohibition of "False and Misleading" Labeling

Under the first prong of *Central Hudson*, FDA may permissibly ban false or misleading labeling.[420] FDA should tread carefully in this area, however. Only speech that cannot be cured of its misleading quality with disclaimers and other changes is "inherently" misleading and therefore proscribable.[421] According to the Supreme Court, the agency may not employ "rote invocation of the words 'potentially misleading'" to justify a total ban, and it is a rare circumstance when an entire class of speech can be declared misleading.[422] Thus, the agency should evaluate most forms of speech on a case-by-case basis to determine if they are individually misleading.[423]

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[417] *See, e.g.*, United States v. Playboy Entm't Group, Inc., 529 U.S. 803, 813 (2000); Evans & Friede, *supra* note 48, at 380-381.

[418] Miller v. Johnson, 515 U.S. 900, 920 (1995); Evans & Friede, *supra* note 48, at 381.

[419] *Playboy*, 529 U.S. at 813.

[420] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 557, 566 (1980).

[421] *See In re* R.M.J., 455 U.S. 191, 206-207 (1982).

[422] Ibanez v. Fla. Dep't. of Bus. & Prof'l Regulation, Bd. of Accountancy, 512 U.S. 136, 146 (1994); Edenfield v. Fane, 507 U.S. 761, 776 (1993).

[423] *See Cent. Hudson*, 447 U.S. at 566 (requiring evaluation of each "regulation" and therefore suggesting that each must be evaluated on its own facts); *see also* Comments of Nat'l Venture Capital Ass'n, *supra* note 226, at 13 ("FDA must be able to point to concrete evidence that particular press releases are misleading or [false].").

c. The Framework Applied: Other Prohibitions

FDA's ban on factual labeling information—such as its ban on mentioning food ingredient sources in the Nutrition Facts Panel[424]—will likely not pass constitutional muster in most cases. This information does not relate to an illegal practice. Thus, to justify a ban under the governing case law, FDA would need to demonstrate, with evidence, that this labeling information cannot be expressed in a nonmisleading way. It seems the agency has not concluded this information would be misleading let alone proven so, as required by Supreme Court precedent. Furthermore, it is not clear what governmental interest these restrictions further, and FDA does not appear to have generated the needed evidence to show direct advancement. Finally, FDA could use a lesser speech restriction—such as required disclaimers or qualifying language—that would address any perceived misleading quality of these factual statements. Thus, a ban is more extensive than necessary, and violates the Supreme Court preference for disclosure over suppression. In sum, FDA's ban on factual information in labeling is likely unconstitutional.

Similarly, it seems unlikely that FDA can completely ban all statements of opinion about required warnings and efficacy.[425] If an individual statement is factually false or inherently misleading, FDA may permissibly ban it. Some of these statements will only be potentially misleading, however, and their misleading quality can be cured by disclaimers. In these situations, a total ban is inappropriate. FDA has a substantial interest in preventing false and misleading speech and ensuring safe and effective use of products. It has not shown direct advancement with evidence, and a ban is more extensive than necessary. Again, FDA must utilize affirmative disclosure requirements to ensure consumers are not misled by these statements, rather than a ban. The FDA qualified health claims Guidance for conventional food and dietary supplements provides analogous doctrine that can serve as a model for these claims.

FDA may, however, be able to limit the number of claims and accompanying disclaimers on a label to avoid information overload.[426] Manufacturers could in theory provide so much information on a label that people would choose not to read it.[427] If FDA could provide evidence that the information overload phenomenon occurs, it could limit the amount of information allowed in a given label. This restriction would be permissible because it would directly advance FDA's important interest in ensuring that safety and efficacy information are readily understandable, and no less restrictive way would be available to ensure that information overload does not occur.

3. *Affirmative Requirements*

This section considers the constitutional propriety of 1) affirmative labeling requirements, and 2) premarket clearance of labeling.

a. Applicable Framework

The first issue is whether the affirmative requirements for labeling are regulation of speech or regulation of conduct. One view is that FDA's regulation of drug

[424] *See supra* note 30 and accompanying text.

[425] See *supra* note 62 and accompanying text.

[426] *See* Comments of the American Association of Retired Persons (AARP) in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C40, at 8-10 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d26.pdf.

[427] *See id.*

labeling information is part of "FDA's determination [whether] drugs … can be safely and effectively used for their intended purposes," and is therefore "ancillary to FDA's regulation of manufacturers' *conduct*."[428] Other commentators argue for application of the compelled commercial speech framework, characterized by application of either *Zauderer*'s "reasonably related" language or the *Central Hudson* test.[429]

Courts will probably find that the compelled speech framework applies in these situations. Because much speech concerns safety and efficacy of a product, courts are unlikely to consider the relationship of labeling to safety and efficacy as sufficient to render labeling as conduct. Furthermore, a court would likely distinguish labeling from the situation in *O'Brien*, where the law restricted an action (burning draft cards), not the content of written or spoken speech like labeling. As in *Washington Legal Foundation*, then, courts will probably find that the labeling is speech, not conduct.[430]

Whether the compelled speech is "commercial" is a more difficult question. Though the *Bolger* test does not neatly apply to compelled speech, the information in the labeling is conveyed for the purpose of fulfilling FDA requirements so that the product may be sold. Hence, it is done for economic reasons and refers to a specific product. It is not clear, however, whether the speech is meant to draw attention to the product specifically, as required by the definition of "advertisement" discussed above.

Under the Supreme Court's analysis in *United Foods*, where it analyzed a statute requiring mushroom producers to contribute money for common advertising and promotion activities, compelled speech should probably be analyzed under the commercial speech regime.[431] Though the compelled speech at issue in *United Foods* (compelled "assessments" from mushroom manufacturers to pay for mushroom advertising) was more paradigmatically commercial than labeling, as Samp notes, "a consensus is emerging that, in most cases, FDA restrictions on manufacturer speech about their products are going to be judged under commercial speech standards."[432] Though this assumption may occasionally give way to speech that concerns pure science, when the speech is attached to or accompanies the product or otherwise supplements its use, and may thus induce consumers to buy it, courts are likely to view it as commercial speech.

FDA recently found that "the agency need not satisfy the *Central Hudson* test" for compelled speech "because that test applies to prohibitions on speech, and not compelled commercial speech."[433] Though the doctrine on compelled commercial speech is still developing, courts are unlikely to agree with FDA on this point. *Cen-*

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[428] Comments of Pfizer, *supra* note 194, at 76 (emphasis added); *accord* Evans & Friede, *supra* note 48, at 394.

[429] *See* Comments of AARP in response to Request for Comment, Docket No. 02N-0209, Comment C89, at 2-4 (Oct. 28, 2002), http://www.fda.gov/ohrms/dockets/dockets/02n0209/02n-0209-c000089-vol19.pdf; Comments of Consumer Healthcare Prods. Ass'n, *supra* note 127, at 2-3; Comments of Food Distribs., Int'l in response to Request for Comment, Docket No. 02N-0209, Comment C92, at 1-3 (Oct. 28, 2002), http://www.fda.gov/ohrms/dockets/dockets/02n0209/02n-0209-c000092-vol19.pdf (arguing for application of *Central Hudson* to disclaimer requirements).

[430] Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51, 59 (D.D.C. (1998)).

[431] United States v. United Foods, 533 U.S. 405, 408, 410 (2001) (implicitly assuming that the speech was commercial in discussing the proper test for commercial speech, and also noting "[t]he fact that the speech is in aid of a commercial purpose does not deprive respondent of all First Amendment protection").

[432] Samp, *supra* note 197, at 314.

[433] Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41,434, 41,440 (July 11, 2003).

tral Hudson—not *Zauderer* and its "reasonable relation" requirement or any other standard—will likely govern the propriety of compelled commercial speech. Both the Supreme Court decision in *United Foods* and *Amestoy* suggested *Central Hudson* would apply.[434] The *United Foods* decision occurred long after that in *Zauderer*,[435] and the Court has applied *Central Hudson* consistently after *Zauderer*.[436] AARP's attempt to distinguish *United Foods* probably will not win the day in court. AARP argues that the regulations in *United Foods* were not part of a "broad regulatory scheme" while FDA's regulations are, but this argument was found unpersuasive in *Washington Legal Foundation*. Furthermore, the Supreme Court has applied *Central Hudson* to speech in heavily regulated settings like speech relating to alcohol in *Rubin* and *44 Liquormart*. In sum, courts will probably apply *Central Hudson* to the compelled speech at issue.

The required preclearance of drug and device labeling is a prior restraint, and courts likely will view the labeling at issue as commercial speech as discussed above, so *Central Hudson* applies.

b. The Framework Applied: Affirmative Labeling Requirements

Affirmative labeling requirements are generally constitutional. First, affirmative disclosures satisfy prong one of the *Central Hudson* test. The required disclosures do not concern an illegal activity; in contrast the speech is mandated by the government. Second, the speech is generally *not* false or misleading. On the contrary, affirmative requirements often are enacted to ensure that labeling is not false and misleading.[437]

Affirmative labeling requirements generally serve important state interests. They provide the person who most needs information about a product—the doctor in the case of prescription products and otherwise the consumer—with the necessary information to use the product safely, effectively and healthfully.[438] In addition, labeling disclosures help the consumer assess the economic value of the product and avoid economic exploitation, recognized as a "substantial interest" in *Fox*.[439] Most affirmative labeling obligations are relevant to health, safety, nutrition or health, and therefore further a "substantial interest."

Courts may find that some disclosure obligations do not address "real" harms—such as obligations aimed at satisfying the public's "right to know" or mere consumer curiosity—and hence do not satisfy the second prong.[440] For example, the current irradiation disclosure requirement for food is likely to fail on this logic, because irradiation has little or no effect on shelf life or the properties of the food, and

[434] *See United Foods*, 533 U.S. at 410; (discussing the *Central Hudson* approach to analysis of speech restrictions, noting disagreement among the Court about whether more rigorous review should apply, and noting that under either *Central Hudson* or more rigorous review the compelled speech at issue was constitutionally infirm); Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 71-73 (2d Cir. (1996)). *United Foods* did state it was "not inconsistent with . . . *Zauderer*," 533 U.S. at 416, but the Court recognized that *Central Hudson* is the governing precedential framework for commercial speech, including in this compelled speech case. *Id.* at 410.

[435] *See United Foods*, 533 U.S. at 405 (decided 2001); Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 626 (1985) (decided (1985)).

[436] *See, e.g.*, Thompson v. W. States Med. Ctr., 535 U.S. 357, 368 (2002) (applying *Central Hudson*).

[437] *See In re* R.M.J, 455 U.S. 191, 203 (1982); Bates v. State Bar of Ariz., 433 U.S. 350, 375 (1977).

[438] *See* Evans & Friede, *supra* note 48, at 394.

[439] Bd. of Trustees of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 475 (1989).

[440] *Amestoy*, 92 F.3d at 73; *see* Edenfield v. Fane, 507 U.S. 761, 770-771 (1993).

FDA does not even uniformly treat irradiated foods as "processed."[441] As such, the disclosure requirement does not seem related to any health, safety, or economic harm, and would likely fail prong two.[442] FDA's proposed rule would address this flaw by requiring irradiation disclosures only when the irradiation caused a material change in the organoleptic (taste, small or texture), nutritional, or functional properties, and allowing alternative labeling language such as "pasteurized."[443] The proposed rule would thus require disclosures that would promote consumer nutrition and ensure that consumers had the necessary information to make a purchasing decision.

Most specific affirmative requirements will be found to directly advance their corresponding substantial governmental interests, and be the least restrictive means of accomplishing these goals. As several commentators note, the use of affirmative labeling requirements is the "most direct way" to advance the government's interests, because it is the only realistic method for conveying health, safety, efficacy, nutrition, and economic information about products.[444] Affirmative labeling requirements are highly effective because they locate the information where its intended audience is most likely to look: in the label or labeling.[445] Courts may, however, push FDA for evidence of these points under *Edenfield*.

For the same reasons, courts will likely find that affirmative disclosures are the least restrictive alternative. There are no plausible non-speech-based alternative ways to convey this crucial information to its intended audience.[446] Further, the speech restriction is of the preferred form: disclosure, not prohibition.[447] Though each affirmative requirement must be analyzed individually, those that require information about safety, efficacy, nutrition, and economic considerations, among other topics, will generally pass *Central Hudson*. Only when the affirmative disclosure requirements are "unjustified or unduly burdensome" under *Zauderer* will they likely be found unconstitutional.

FDA conducted similar analysis in a recent rulemaking to establish new requirements for the physician labeling for prescription drugs.[448] FDA found that its disclosure requirements satisfied *Central Hudson*. FDA stated that risk information and warnings are necessary to ensure that labeling is nonmisleading. FDA also found that other labeling requirements that are not necessary to prevent misleading speech nonetheless fulfilled *Central Hudson*. According to FDA, these restrictions address interests previously recognized as "substantial": "ensuring the safe and effective use of prescription drug products" and promoting the public health. They "directly advance" these interests because they ensure that the drugs are prescribed and used safely and effectively. FDA found the fourth prong satisfied because of a lack of "numerous and obvious" regulatory alternatives to communicating key information besides labeling. FDA found that neither education campaigns nor mere

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[441] *See supra* note 24 and accompanying text; *see also* Comments of Food Distribs., Inc., *supra* note 429, at 1-3.

[442] *See* Comments of Food Distribs., Inc., *supra* note 429, at 1-3.

[443] Irradiation in the Production, Processing, and Handling of Food, 72 Fed. Reg. 16,291, 16,293-16,294 (proposed Apr. 4, 2007).

[444] Comments of Pfizer, *supra* note 194, at 78-79; *see also* Comments of AARP, Comment C89, *supra* note 429, at 4 (discussing prevention of consumer deception).

[445] Comments of Pfizer, *supra* note 194, at 78.

[446] *Id.* at 78-79.

[447] *In re* R.M.J., 455 U.S. 191, 203 (1982); Bates v. State Bar of Ariz., 433 U.S. 350, 375 (1977).

[448] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,964 (Jan. 24, 2006).

"encourag[ement]" of manufacturers to provide voluntarily the information would achieve the interests as well. FDA also concluded that its restrictions fulfilled the alternative *Zauderer* test because the required disclosures are "necessary" to ensure that crucial drug information reaches the intended audience and thus, the rules "do not impose 'unjustified or unduly burdensome' disclosure requirements."

In other preambles, however, FDA has assumed that failure to make certain disclosures (like trans fat content) renders a label automatically misleading.[449] This latter reasoning is less likely to survive judicial review under *Central Hudson* because the agency may not use "rote invocation" of the words "potentially misleading," but must offer evidence substantiating the labeling's misleading character.[450] Courts would likely look for FDA to utilize similar analysis as in the drug labeling rule coupled with evidence on the third prong to substantiate its rule.

c. The Framework Applied: Pre-sale Approval of Labeling

Under *Central Hudson*, the premarket approval requirement for labeling is also likely constitutional. The speech does not concern illegal activity because the underlying sales involve approved products.[451] Furthermore, the speech at issue — proposed additional or different labeling content—is not generally false or misleading. Again, the agency has a substantial governmental interest in mind: ensuring that drugs and devices are used safely and effectively.[452] A court will probably find that the regulation directly advances this interest because it allows FDA to confirm that the labeling will enable safe and effective use *before* it is ever used. Both prongs three and four are likely fulfilled because the government compiled an extensive record of evidence before concluding that premarket approval was warranted, including evidence that showed other alternatives to premarket approval, such as disclaimers, were ineffective.[453] Though prior restraints are disfavored in comparison with the disclosure requirements, the use of prior restraints will probably be found to be justified here because a body of evidence exists that demonstrates this is the least restrictive effective means of accomplishing crucially important governmental goals. As such, the premarket labeling clearance requirement is likely to pass *Central Hudson* scrutiny.

4. *Format Specifications*

This section considers the First Amendment propriety of FDA's format and presentation requirements for labels and labeling.

a. Applicable Framework

Presentation can be a key method of expression, and therefore, receives First Amendment protection.[454] The speech at issue here is likely "commercial" in nature for the same reasons discussed above as to labeling language. As such, *Central Hudson* apparently applies.

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[449] *E.g.,* Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims, 68 Fed. Reg. 41,434, 41,439-41,341 (July 11, 2003).

[450] Ibanez v. Fla. Dep't. of Bus. & Prof'l Regulation, Bd. of Accountancy, 512 U.S. 136, 146 (1994).

[451] Comments of Pfizer, *supra* note 194, at 76.

[452] *See id.* at 78.

[453] *Id.* at 79; Comments of Sen. Kennedy et al., Congress of the United States, in response to Request for Comment, Docket No. 02N-0209, Comment C65, at 6-21 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091802/80027f41.pdf.

[454] *Cf.* Cohen v. California 403 U.S. 15, 21-22 (1971) (finding "mode of expression" key to First Amendment rights).

b. The Framework Applied

The speech at issue does not relate to illegal sales. Unformatted and unorganized language could be misleading, but FDA would bear the burden of proof to demonstrate this phenomenon with evidence. Assuming that it cannot (because this is a high burden), ordinary *Central Hudson* analysis applies. FDA has four central "substantial interests" in formatting regulations: 1) ensuring that labeling is nonmisleading; 2) guaranteeing readability of the labeling for safe and effective use of products; and 3) conveying information to consumers to aid in dietary and other health-related choices; and 4) avoidance of economic exploitation.[455]

The format requirements likely directly advance these interests by requiring uniform labeling.[456] Uniform formatting renders labeling more legible and comprehensible, allows physicians and consumers to access important information readily, and enables quicker comparison of products.[457] FDA has a body of empirical evidence to demonstrate these contentions. As Pfizer notes, "[n]umerous studies demonstrate that presenting information concerning a particular product in a uniform manner across all products … enables readers more easily to digest that information" and locate relevant data.[458] FDA has utilized such studies to justify its formatting requirements.[459]

In most cases, courts will probably find that no less restrictive alternatives exist. There are no alternatives to this regulation that do not involve speech.[460] Further, there are typically no less restrictive formatting alternatives. FDA considers a variety of formats for given labeling and chooses one on the basis of readability, labeling costs, and safety and efficacy considerations.[461] The formatting requirements are geared at ensuring *uniformity*, so even though other specific formats might accomplish the aims in an equally effective manner, FDA must select one font size, organization, etc., to advance its goal.[462] This conclusion is in keeping with *Virginia Pharmacy* dicta noting that it is "appropriate to require that a commercial message appear in such a form … as are necessary to prevent its being deceptive."[463] Therefore, formatting regulations are likely generally constitutional.

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[455] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,964 (Jan. 24, 2006) ("FDA believes that much information required to appear in prescription drug labeling is necessary for labeling to be nonmisleading."); Evans & Friede, *supra* note 48, at 396-397; Comments of Va. Polytechnic Inst. & State Univ. in response to Request for Comment, Docket No. 02N-0209, Comment C71, at 5 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091802/80027f57.pdf; *see also* Bd. of Trustees of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 475 (1989).

[456] *E.g.,* 21 C.F.R. § 101.9(d); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,964.

[457] Comments of AARP, Comment C40, *supra* note 426, at 12 ("Specific format requirements address the needs of particularly vulnerable consumers—like older consumers who may have impaired vision and cognitive abilities—and should be tested to determine which ones best ensure readability."); Comments of Ass'n of Food & Drug Officials in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C59 at 3 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091702/80027f36.pdf (noting "standardized panels" are helpful in conveying information); Comments of Council for Responsible Nutrition, *supra* note 128, at 4 ("A standard location and format for warnings, such as that adopted in OTC labeling may be helpful in facilitating consumer use."); Comments of Pfizer, *supra* note 194, at 83.

[458] Comments of Pfizer, *supra* note 194, at 84 n.286, 287 (collecting studies).

[459] *See, e.g.*, 71 Fed. Reg. at 3,985-86 (citing to a number of studies about format impact).

[460] Comments of Pfizer, *supra* note 194, at 85.

[461] *See, e.g.*, 71 Fed. Reg. at 3,985 (discussing and rejecting labeling alternatives).

[462] Comments of Pfizer, *supra* note 194, at 85.

[463] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 772 (1976).

An exception exists when these formatting requirements become unduly burdensome.[464] In *Discovery Network*, the Supreme Court indicated that a speech restriction will violate the fourth prong if "numerous and obvious less-burdensome alternatives" existed.[465] If the agency can fulfill its goals—ensuring non-deceptive speech, guaranteeing readability, ensuring that consumers have needed information, promoting uniformity and avoiding economic exploitation—through less burdensome formatting requirements, a court will likely find that the agency must do so.

5. *"Exclusivity" in Specific Labeling Language*

This section considers whether FDA may specify the precise language that a manufacturer must use in labeling.

a. Applicable Framework

The dictation of specific wording and permission of only that wording can be viewed as both a speech prohibition (in that other wording is not permissible) and a compelled speech requirement (in that specific wording is required). This speech will likely be considered commercial, for the same reasons articulated in the context of affirmative labeling requirements, and courts will likely apply *Central Hudson* as discussed above.

b. The Framework Applied

FDA's specificity policy is likely unconstitutional. The speech at issue does not pertain to illegal activity and is not false or misleading.[466] FDA's substantial interest at issue is to facilitate the safe, healthful and effective use of various products.[467] The specificity policy is distinguishable from its formatting policy as to prongs three and four, however. While FDA has a body of data demonstrating that its formatting requirements aid consumer comprehension in various settings,[468] its evidence for specific wording is mixed and more fact-specific. In some cases, this evidence weighs *against* specificity increasing comprehension. For example, one study cited by FDA showed that consumers could not distinguish between various phrases for describing product efficacy ("generally effective," "usually effective" and "moderately effective" were all taken to have the same meaning).[469] This evidence weighs against FDA's position that specificity in language increases consumer comprehension because it shows that one prescribed phrase will not necessarily be more useful than any other in increasing consumer comprehension. When its evidence as to prescribed warnings tilts against the agency, FDA cannot fulfill prong three.

Even in situations where FDA can produce evidence showing a specific warning or labeling statement increases consumer comprehension, a court will likely find that less restrictive alternatives are available. FDA can allow the use of synonyms and can create an optional safe harbor for use of the exact language.[470] These

[464] *See* Ibanez v. Fla. Dept. of Bus. & Prof'l Reg., Bd. of Accountancy, 512 U.S. 136, 146-147 (1994); Comments of Pfizer, *supra* note 194, at 85-86.

[465] City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 418 n.13 (1993).

[466] Comments of Pfizer, *supra* note 194, at 89.

[467] *See id.*

[468] *See supra* note 459.

[469] Kathryn J. Aikin, FDA, Consumer Comprehension and Preference for Variations in the Proposed Over-the-Counter Labeling Format: Final Report, Docket No. 96N-0420, at 47 (1998).

[470] *See* Comments of Consumer Healthcare Prods. Ass'n, *supra* note 127, at 5; Comments of Pfizer, *supra* note 194 at 91-92.

alternative policies would further FDA's goals to the same extent as the specificity policy because FDA already controls labeling substance.[471] Thus, labeling will already have essentially the same content even without the specificity policy. This contrasts the situation from that of formatting requirements, where the absence of these requirements would likely force consumers would have to search all over the box to find the information they need. Consequently, consumers will receive the needed information even without the specificity policy, and there is "no constitutional justification for mandates that direct precise word choice."[472]

Furthermore, a court will likely find that FDA's own enforcement policy shows that less restrictive alternatives to the specificity policy are available.[473] In the OTC context, FDA permits deviation from a tentative final monograph unless the labeling language poses a "potential hazard to health."[474] FDA apparently believes that alternative language can adequately serve its interests except in certain narrow circumstances. Therefore, such alternative language is a less restrictive means of accomplishing the agency's goals than the exact language policy.

D. *Claims*

1. *Issues*

First, this section considers whether the restrictions on claims constitute speech restrictions or are simply evidentiary uses of speech. As discussed in part IV(A) above, courts will likely find that use of speech to infer the manufacturer's intended use for the products, and consequently, the product's classification, is not a speech restriction. Using the same logic, FDA and the *Whitaker* court found the frameworks for health claims and dietary supplement structure-function claims do not impose speech restrictions, because failure to comply with the FDA rules simply renders the product a drug, and does not ban the claim.[475]

In contrast, commentators contend that use of speech as a "trigger" for requiring FDA approval of a new drug constitutes a speech restriction in view of *Western States*, where the Supreme Court found that predicating an exemption from the new drug approval provisions on lack of advertising was a restriction on speech.[476] *Pearson* resonates with this conclusion, because the court there found it "undisputed" that conditioning safe harbor protection on abstention from certain speech was a speech restraint requiring *Central Hudson* analysis.[477]

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[471] Evans & Friede, *supra* note 48, at 400.

[472] *Id.*

[473] *See* Comments of the Cosmetic, Toiletry, and Fragrance Ass'n (CTFA) in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C34, at 12, 17-18 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d20.pdf.

[474] FOOD AND DRUG ADMINISTRATION, COMPLIANCE POLICY GUIDE 7132b.15 § 450.200 (1995), *available at* http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg450-200.html.

[475] Whitaker v. Thompson, 353 F.3d 947, 953 (D.C. Cir. (2004)); Regulations for Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1,000, 1,038 (Jan. 6, 2000) (noting that barring some structure-function claims "does not prohibit any speech" but instead "clarifies the circumstances under which FDA will consider a certain type of speech—labeling claims—to be evidence of intended use as a drug … . Thus, the rule does not regulate speech as such, but rather as evidence of intended use").

[476] Comments of Nat'l Food Processors Ass'n in response to Request for Comment on First Amendment Issues, Docket No. 02N-0209, Comment C33, at 2 (Sept. 13, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d1f.pdf.

[477] Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. (1999)).