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First Amendment Scrutiny of FDA'S Fight Against Misbranding: Placing Labeling on the Spectrum of Speech

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I. Introduction

In order to further the Food and Drug Administration's (FDA) mission of assur[ing] that the products it regulates are safe and truthfully labeled,¹ the Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA the power to enforce prohibitions on labeling that causes a food, drug, cosmetic, or medical device to be misbranded.² The FD&C Act defines labeling as all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.³ Because of the expansive nature of this definition, independently written pamphlets, newspapers, and books that accompany products covered by the FD&C Act constitute labeling in certain circumstances. This exacerbates the tension between the First Amendment's free speech guarantee and FDA's mandate, and raises the question of how courts should scrutinize FDA's ability to seize or enjoin the sale of misleading labeling.⁴ The importance of both the Free Speech Clause and the protection of consumers makes this a difficult issue to resolve, and as of yet,

¹PETER BARTONHUTT & RICHARD A. MERRILL, *FOOD AND DRUGS* 5 (2d ed. 1991).

²Federal Food, Drug, and Cosmetic Act (Hereinafter "FD&C Act"), §§ 301(a), 301(g), 301(k) (1938).

³*Id.* at § 201(m).

⁴This paper will focus exclusively on the type of labeling that falls within the second clause of the definition, since the categorization of independent written matter as labeling emphasizes the First Amendment issue.

no case has squarely confronted the issue.⁵

The analysis of constitutional limitations on FDA's anti-misbranding powers turns on how the Supreme Court would classify labeling: is it a distinct category of regulated speech, commercial speech, or ordinary speech? FDA has advocated the classification of labeling as a distinct category of regulated speech, but there is little authority or logic to support this position, and the First Amendment tradeoff of such a classification would be too great. The evidence suggests that the Court would almost definitely deal with labeling as commercial speech, but should instead treat it as ordinary speech. By treating labeling as ordinary speech, the Court can circumvent the myriad infirmities of the commercial speech doctrine, while providing an acceptable balance between the First Amendment and consumer protection.

II. The Scope of Labeling

In order to keep the proverbial horse before the cart, it is necessary to establish exactly what speech is at issue before considering what level of protection the Supreme Court should afford it. The Wheeler-Lea Act of 1938⁶ gave the Federal Trade Commission jurisdiction over the advertising of food, drugs, devices, and cosmetics, while FDA retained power to regulate the labeling of these items.⁷ Thus, the threshold inquiry in an apparent misbranding case is whether the written matter at issue is advertising or labeling.

⁵HUTT & MERRILL, *supra* note 1, at 49.

⁶52 Stat. 111, 114 (1938). The Wheeler-Lea Act was later incorporated into 15 U.S.C. SS52658.

⁷Congress subsequently granted FDA the power to regulate advertising for prescription drugs, FD&C Act, S502(n); and vitamins and minerals, *Id.* at SS403(a)(2), 707.

The statutory definition of labeling quoted in the introduction⁸ is amazingly broad and flexible, and can include virtually anything that accompanies a food, drug, device, or cosmetic. This flexibility is enhanced by the fact that courts construe the FD&C Act liberally when determining whether something constitutes labeling: since the Act is designed to prevent injury to the public health, the rule of strict construction does not apply.⁹ To most people, it is probably counterintuitive to consider books written by independent authors as labeling, but the connection becomes more apparent if one imagines the following scenario. On the shelves of a health food store, jars of honey are surrounded by About Honey, a booklet written by an author who has no connection to the store or the honey manufacturer. In addition, copies of a newsletter containing an article entitled Eat Honey and Increase Your Vitality are on the store premises. When a prospective customer asks for information about honey, a store employee shows him the book and the pamphlet. The literature contains unsubstantiated claims that herald honey as a panacea for various diseases and ailments that have plagued man from time immemorial.¹⁰

This very fact pattern was at issue in *United States v. 250 Jars 'Cal's Tupelo Blossom U.S. Fancy Pure Honey'*.¹¹ In upholding the District Court's determination that the literature in question constituted labeling, the Sixth Circuit reasoned that the FD&C Act was passed to protect unwary cus-

⁸See *supra* note 3 and accompanying text.

⁹*United States v. Research Laboratories*, 126 F.2d 42, 45 (9th Cir. 1942). See also *United States v. Urbuteit*, 335 U.S. 355, 358 (1948) (The problem is a practical one of consumer protection, not dialectics).

¹⁰*United States v. 250 Jars 'Cal's Tupelo Blossom U.S. Fancy Pure Honey'*, 344 F.2d 288, 289 (6th Cir. 1965).

¹¹*Id.*

tomers in vital matters of health and, consequently, must be given a liberal construction to effectuate this high purpose.¹² Failing to take action against this book and newsletter duo would be tantamount to open[ing] a loophole through which those who prey upon the weakness, gullibility, and superstition of human nature can escape the consequences of their actions.¹³

A more coordinated use of a book as labeling was at issue in *United States v. 8 Cartons 'Plantation 'The Original' etc. Molasses'*.¹⁴ In this case, copies of a book touting alleged benefits of blackstrap molasses were placed in a health food store window along with several jars of the molasses. The display further featured a sign that informed potential customers that they could order all products for the Hauser diet and purchase blackstrap molasses from the store, and should Come in for full information.¹⁵ In response to inquiries, the store handed customers a copy of the book and referred them to the pages therein that discussed blackstrap molasses. Given this overwhelming evidence of the store's use of the book to sell molasses, the court had no difficulty in concluding that the book constituted labeling.¹⁶

As the *Cal's Honey* and *Plantation Molasses* cases and the FD&C Act definition indicate, the determining factor in whether to classify written matter as labeling is whether it accompanies the article it describes. In *Kordel v. United States*,¹⁷ the U.S. Supreme Court held that the phrase 'accompanying

¹²*Id.*

¹³*Id.*

¹⁴103 F.Supp 626 (W.D.N.Y. 1951).

¹⁵*Id.* at 627.

¹⁶*See Id.* at 628.

¹⁷335 U.S. 345 (1948).

such article' is not restricted to labels that are on or in the article or package that is transported.¹⁸ Instead, the Court took the view that it is the textual relationship between the written matter and the product that is important: one thing accompanies another when it supplements or explains it.¹⁹

If labeling is not restricted to the writing that is physically attached to a product's container,²⁰ what are its limits? Clearly, There is a line to be drawn, and labeling cannot include every writing which bears some relation to the product.²¹ In *United States v. 24 Bottles 'Sterling Vinegar and Honey,' Etc.*,²² although a store sold Vinegar and Honey mixtures and two books making bold claims about such mixtures, the Second Circuit held that the books did not constitute labeling, since there was no evidence of any joint promotion of either book with Vinegar and Honey.²³ While the books undoubtedly helped

¹⁸*Id.* at 349. *See also* V.E. Irons, Inc. v. United States, 244 F.2d 34, 39 (1st Cir. 1957) ('labeling' must be given a broad meaning to include all literature used in the sale of food and drugs, whether or not it is shipped into interstate commerce along with the article); *United States v. 7 Jugs, etc. 'Dr. Salsbury's Rakos'*, 53 F.Supp. 746, 755 (D.Minn. 1944) (The mere fact that the products were shipped at a different time, over a different route and were received at a different time from the booklets should not be permitted to confuse or obscure the substance of the matter).

¹⁹335 U.S. at 350. The Third Circuit has gone even farther, holding that, if the literature is obviously printed for use generally in promoting the sale of the [product], there is no requirement that the literature actually had been used as labeling, *i.e.*, that it had been used in connection with selling the product. *United States v. 47 Bottles 'Jenasol R.J Formula '60'*, 320 F.2d 564, 569 (3rd Cir. 1963).

²⁰In *Nature Food Centres v. United States*, 310 F.2d 67 (1st Cir. 1962), the appellant turned the tables, and claimed that independent leaflets satisfied the FD&C Act's affirmative branding requirements for various dietary supplements sold in their stores. The court rejected this argument, since the leaflets were only available for a fee at various nutrition lectures, and were not available at the stores: although by 'accompanying' documents a defendant may incur liability for false labeling even though they do not accompany all the products, this does not mean that independent documents can satisfy affirmative labeling obligations with respect to those products they do not accompany. *Id.* at 70671. *See also* *Alberty Food Products Co. v. United States*, 194 F.2d 463 (9th Cir. 1952) (It is not sufficient that the labeling contain a minimum of information and the use of the drug be induced by elaborate collateral representations. To permit the operation of such an escape valve would render the aims and purposes of labeling requirements nugatory).

²¹*United States v. 24 Bottles 'Sterling vinegar and Honey,' Etc.*, 338 F.2d 157, 158 (2nd Cir. 1964).

²²*Id.*

²³*Id.* at 159.

the store to sell the product, they were in the literature section of the store, no displays featured both the books and the product, and the store sold one of the books for two years prior to carrying the product. Thus, although the books made unsubstantiated claims, the claims were not made in immediate connection with the sale of the product.²⁴ As a result, there was no violation of the FD&C Act, which was not intended to deal generally with misleading claims.²⁵

The vague language of the FD&C Act can clearly lead to fact-specific battles over whether a particular book labels a product. Assuming that a book does constitute labeling, it misbrands the accompanying product if it is false or misleading in any particular.²⁶ As with labeling, statutory language that is both broad in scope and short on details is likely to generate heated debate over whether information is misleading. The delivery of a misbranded food, drug, device, or cosmetic for introduction into²⁷ interstate commerce, or the misbranding of such an item during²⁸ or after²⁹ interstate commerce, and the receipt³⁰ in interstate commerce of a misbranded item are all prohibited by the FD&C Act. When such violations occur, FDA is empowered to undertake injunction proceedings³¹ and seize³² the misbranded items. Further elaboration

²⁴*Id.* at 160.

²⁵*Id.*

²⁶The FD&c Act contains identical language in the provisions dealing with misbranded food (S403(a)); drugs and devices (S502(a)); and cosmetics (S602(a)). The statute also provides long lists of specific ways in which labeling can misbrand products.

²⁷FD&C Act S301(a).

²⁸*Id.* at S301(b).

²⁹*Id.* at S301(k).

³⁰*Id.* at S301(c).

³¹*Id.* at S302.

³²*Id.* at S304.

on the intricacies of classifying books as labeling and/or misleading is beyond the scope of this paper; now, the discussion turns to where on the spectrum of speech the Supreme Court might place labeling.

III. Labeling and the First Amendment's Protection of Speech

What are the implications of the First Amendment's free speech protections for FDA's powerful anti-misbranding weapons? Given the fairly broad statutory language, FDA's significant power, and the sensitive nature of limitations on speech, it is surprising that no case has squarely confronted the issue³³ of constitutional limitations on FDA's ability to restrict the sale of independently written books used as labeling.³⁴ It is clear that at some point, the First Amendment's protection of free speech limits the power of government to regulate the content of labeling for food and similar products; the difficulty is in defining this limitation.³⁵

The Supreme Court has constructed a tiered system of speech, deeming some forms of speech more worthy of protection than others. Thus, the limits placed on FDA's regulatory power will be a function of the category of speech in which the Court places labeling. Judging from precedents in analogous areas, this would most likely be one of three categories: a distinct category

³³HURT & MERRILL, *supra* note 1, at 49.

³⁴The fact that there has been no direct confrontation is due in part to the revision of FDA policy in 1982. Although it still seizes labeling other than books, FDA no longer seizes books along with misbranded products; instead, when a book misbrands a product, FDA will consider filing an injunction to halt, after a hearing, the misuse of the book. FDA Compliance Policy Guide 7153.13 (Issued Dec. 1, 1932; Revised Aug. 31, 1989). FDA apparently changed its policy in response to the fear that it would be vulnerable to attack on First Amendment grounds. *See United States v. An Article of Drug on the Premises of DMSO, Inc.*, 1983-1984 FDLI Jud. Rec. 1 (W.D.N.Y. 1983). Of course, FDA may at any time change its view on how it should pursue books, and this paper will occasionally use the term book as a generic term for independent written matter.

³⁵HURT & MERRILL, *supra* note 1, at 49.

of regulated speech, commercial speech, or pure speech.

A.A Distinct Category of Regulated Speech

FDA, like any other governmental agency, would love to be able to regulate as it sees fit without having to deal with uncertain and unpleasant limitations on its power. Thus, starting with the modest premise that regulation of food labeling would be impossible if the Government could not restrict speech,³⁶ FDA reached the bold conclusion that its restrictions on food labeling should be subject to the minimal scrutiny that is afforded to the government in certain heavily-regulated areas. The proposed similarity between food labeling and securities, labor, and antitrust regulation is that in each instance, the Government exerts extensive regulatory authority over the surrounding activity and may place restrictions on speech that bear directly on the Government's objectives.³⁷ In other words, since FDA's power to regulate food labeling derives from its broad powers over food, FDA contends that these regulations should be subject to the limited scrutiny that has been afforded restrictions on speech under extensive regulatory schemes involving areas of economic activity.³⁸

There are several problems with FDA's contention that labeling should be treated as a distinct category of regulated speech. First, the only case that FDA legitimately cites to support its contention is *SEC v. Wall*

³⁶58 Fed. Reg. 2478, 2525 (Jan. 6, 1993).

³⁷Edward Dunkelberger & Sarah E. Taylor, *The NLRA, Health Claims, and the First Amendment*, 48 *Food & Drug L.J.* 631, III B (1993). N.E.: Publication page references for this article are not available on Westlaw, and the volume of the journal in which it was printed could not be located in the Harvard Law School library during the weeks of 1/16/95 and 1/23/95, despite the placement of a search request at the Circulation Desk. Thus, references for this article will be to section numbers, not page numbers.

³⁸58 Fed. Reg. at 2527.

Street Publishing Institute,³⁹ a Court of Appeals case which upheld the right of the government to regulate a stock market magazine. Several factors render this case inapposite to food labeling. The *Wall Street* court emphasized that speech relating to the purchase and sale of securities., forms a distinct category of communications, since usecurities regulation is a form of regulation distinct from the more general category of commercial speech.⁴⁰ Nowhere in the course of highlighting the unique nature of the stock market does the court refer to labeling. In addition, the issue at bar was not a restriction on speech, but rather a regulation that required the magazine to disclose that it had been paid to publish certain articles. Furthermore, other than the fact that the government regulates both areas, there is little similarity between food labeling and the stock market, and there is no logical reason why rules applying to one necessarily apply to the other. This does not bode well for FDA's position, since the Supreme Court has been hesitant to transfer narrowly-defined First Amendment restrictions to new contexts⁴¹

Another problem with FDA's contention is that FDA did not justify its need to be able to regulate labeling with only limited scrutiny, *i.e.*, it never asserted why treating labeling as ordinary speech or commercial speech

³⁹851 F.2d 365 (D.C. Cir. 1988), *cert. denied*, 489 U.S. 1066 (1989). FDA implicated only one other case that was decided after *Central Hudson*(see *infra* note 6?): *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749 (1985). which is inapposite. See *Dunkelberger & Taylor*, *supra* note 37, at III B.

⁴⁰851 F.2d at 373.

⁴¹*See, e.g.*, *Bates v. State Bar of Arizona*, 433 U.S. 350, 365 (1977) (The Court, in dealing with restrictions on lawyer advertising, was wary of applying its decision to other contexts: Because of the possibility... that the differences among professions might bring different constitutional considerations into play, we specifically reserved judgment as to other professions. In fact, even within the profession of lawyering, the Court restricted its decision to advertising for price and type of services, not delving into advertising claims of the quality of legal services).

would hamper its efforts to prevent misbranding. Clearly, it must be able to restrict what is said in labeling so that it can protect the public. But why give the surgeon a chainsaw when a scalpel will do? In the case of labeling, the scalpel (more fine-tuned power to regulate speech) is powerful enough to do the job (as we will see later), while the chainsaw (nearly unrestricted power to regulate speech) is too strong and may consequently suppress speech the First Amendment should protect. If one accepts the proposition that a regulatory agency should have only the power it needs to perform its function, especially when important rights are at stake, it is axiomatic that it is undesirable, and perhaps dangerous, to empower an agency to go beyond its calling.

The *Wall Street* case itself provides an example of the highly limited scrutiny that regulations face when the speech involved is a category of regulated speech. The court did[N]ot think it necessary... to inquire, as we would if only commercial speech were involved, whether the government's specific regulatory objective... is constitutionally permissible. In areas of extensive regulation ó like securities dealing ó we do not believe the Constitution requires the judiciary to weigh the relative merits of particular regulatory objectives that impinge upon communications occurring within the umbrella of an overall regulatory scheme.⁴²

This reasoning, when applied to books used as labeling, could endanger speech that should be protected. For example, if FDA decided to expand significantly its interpretation of what constitutes labeling, a court employing

⁴²851 F.2d at 373.

the above reasoning would be unlikely to second-guess it, and would leave far more books subject to FDA censorship without adequately considering the countervailing First Amendment considerations. Likewise, FDA could run roughshod over books by construing misleading in any particular in a way that would implicate every book that was not comprehensive, easy to understand, fully balanced, and supported by significant scientific data. Should a diet book that labels food be seized if it does not compare the program it advocates with others, or if it claims its plan is an excellent way to trim down, without defining excellent in detail? If the Supreme Court were to analyze restrictions on food labeling as a category of regulated speech, courts would not consider the relative merits of particular regulatory objectives,⁴³ and FDA could remove dozens of books from store shelves.⁴⁴

While deep down FDA does not consider it necessary for its First Amendment analysis to determine whether or not food labeling fits the definition of commercial speech, it has reluctantly recognized that no court has supported its position, and at least one court has categorized labeling as commercial speech.⁴⁵ Because of this, and the difficulties of supporting its preferred position, FDA gave up its unconvincing attempt to classify food labeling as a distinct category of regulated speech, and currently justifies its restrictions on labeling by relying upon the Supreme Court's framework for commercial speech

⁴³*Id.*

⁴⁴Even if the books were mostly useless, such action would seriously restrict our paradigm of a marketplace of ideas, in which ideas succeed or fail on their merits, not by government fiat.

⁴⁵58 Fed. Reg. at 252562526.

cases.⁴⁶

B Commercial Speech

The Supreme Court defined commercial speech in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*⁴⁷ as speech which does 'no more than propose a commercial transaction.'⁴⁸ Commercial speech is currently a middle ground between speech in an extensive regulatory scheme and ordinary noncommercial speech, but this has not always been the case. Until the 1970s, the U.S. Supreme Court assumed that most types of commercial speech ó commercial advertising, or speech that merely proposes a commercial transaction ó fell wholly outside the First Amendment.⁴⁹ In *Valentine v. Chrestensen*,⁵⁰ the grandfather of the commercial speech doctrine, the U.S. Supreme Court stated that the Constitution imposes no... restraint on government as respects purely commercial speech.⁵¹ Thus, in *Eight Cartons 'Plantation etc. tlolasses'*,⁵² decided in the *Valentine* era, the First Amend-

⁴⁶ See Dunkelberger & Taylor, *supra* note 37, at III B.

⁴⁷ 425 U.S. 748 (1976). See also *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66667 (1983), in which the Court held that the fact that pamphlets sent through the mail were conceded to be advertisements clearly does not compel the conclusion that they are commercial speech, even though the pamphlets referred to a specific product. Likewise, the fact that Youngs mailed the pamphlets for economically-motivated reasons would clearly be insufficient by itself to turn the materials into commercial speech. However, the Court held that the combination of these characteristics provided strong support for the District Court's conclusion that the pamphlets should be characterized as commercial speech.

⁴⁸ *Virginia Pharmacy*, 425 U.S. at 762 (quoting *Pittsburgh Press Co. v. Human Relations Com'n*, 413 U.S. 376, 385 (1973)).

⁴⁹ GERALD GUNTHER, *INDIVIDUAL RIGHTS IN CONSTITUTIONAL LAW* 838 (5th Edition 1992).

⁵⁰ 316 U.S. 52 (1942). At issue in *Valentine* was a New York statute that limited the distribution of any handbill, circular card, booklet [or] placard that qualified as commercial [or] business advertising matter. *Id.* at 53, n. 1.

⁵¹ *Id.* at 54. Of course, this did not mean that the First Amendment did not apply simply because the speaker had a commercial motive: the fact that a movie or book is distributed for profit does not mean the First Amendment does not apply. See GUNTHER, *supra* note 49, at 839.

⁵² 103 F.Supp. 626 (W.D.N.Y. 1951).

ment concerns of a book publisher were easily dismissed, since the seizure of its books had not interfered with [their] bona fide sale, *i.e.*, the books were part of a distribution plan to sell molasses, a use tantamount to purely commercial advertising.⁵³

In the early 1970s, the Court actively used the *Valentine* doctrine. Initially, the policy was strengthened in cases such as *Pittsburgh Press Co. v. Human Relations Commission*,⁵⁴ in which the Court upheld a law that prohibited the use of certain classic examples of commercial speech.⁵⁵ However, the Court changed its path in *Virginia Pharmacy*,⁵⁶ in which it invalidated a statute that banned advertising of prescription drug prices as violative of the First and Fourteenth Amendments. The Court abandoned the *Valentine* doctrine of commercial speech for a middle-of-the-road approach: commercial speech no longer lacks all protection,⁵⁷ but there are two types of permissible regulations on it: content-neutral restrictions on the time, place, and manner of the speech,⁵⁸ and the attempt to insure that the stream of commercial information flows cleanly as well as freely.⁵⁹ As for the latter type of regulation, the Court admitted that difficulties will arise, since much commercial speech is not provably false, or even wholly false, but only deceptive or misleading.⁶⁰

⁵³*Id.*

⁵⁴413 U.S. 376 (1973).

⁵⁵*Id.* at 385.

⁵⁶425 U.S. at 748. *See also* *Bigelow v. Virginia*, 421 U.S. 809 (1975).

⁵⁷425 U.S. at 762.

⁵⁸FDA misbranding provisions are content-based, so they are not time, place, or manner restrictions. *See, e.g.*, *Linmark Associates, Inc. v. Township of Willingboro*, 431 U.S. 85, 94 (1977) (A town proscribed the placement of For Sale signs on residential property, based on the fear that the content of such signs would cause other residents to sell their houses. Thus, even though the statute outlawed only one kind of communication, it was not merely a time, place, or manner restriction).

⁵⁹425 U.S. at 771.

⁶⁰*Id.* *See also* *Bates*, 433 U.S. at 383-84 (Two clearly permissible limitations on commercial

Why is commercial speech not worthy of the full protections afforded to noncommercial speech? In *National Commission on Egg Nutrition v. Federal Trade Commission*,⁶¹ the Seventh Circuit reasoned that, in a commercial context, the First Amendment interests of the manufacturer and the consumer are often at odds, and must be balanced. The interest of the consumer in obtaining truthful information about the product is served by insuring that the information is not false or deceptive.⁶² On the other hand, a regulation prohibiting deception is not likely to impede the interests of the manufacturer in disseminating information about its product, for two reasons. First, Since advertising is linked to commercial well-being, it seems unlikely that such speech is particularly susceptible to being crushed by overbroad regulation.⁶³ Second, concerns over the chilling effect on speech of an uncertain regulation are quelled by the fact that an advertiser presumably can determine more readily than others whether his speech is truthful and protected.⁶⁴ Hence, when the interests of the consumers are weighed against the interests of the advertisers, the scale is tipped in favor of regulation.⁶⁵ However, it is still the case that the party seeking to uphold a restriction on commercial speech carries the burden of justifying

speech are restrictions on advertising that is false, deceptive, or misleading, and restrictions on the time, place, and manner of advertising).

⁶¹570 F.2d 157 (7th Cir. 1977).

⁶²*Id.* at 162.

⁶³*Bates*, 433 U.S. at 382.

⁶⁴*Id.*

⁶⁵570 F.2d at 162. See also *Central Hudson Gas & Electric Corporation v. Public Service Com'n of New York*, 447 U.S. 557 (1980) (Two characteristics of commercial speech allow its content to be regulated, even though the First Amendment prohibits content-based regulations in most contexts. First, commercial speakers have extensive knowledge of both the market and their products. Thus, they are well situated to evaluate the accuracy of their messages and the lawfulness of the underlying activity. Second, commercial speech, the offspring of economic self-interest, is a hardy breed of expression that is not 'particularly susceptible to being crushed by overbroad regulation').

it.⁶⁶

In *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*,⁶⁷ the U.S. Supreme Court consolidated its commercial speech jurisprudence into a four-part analysis:

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. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.⁶⁸

In *Board of Trustees of the State University of New York v. Fox*,⁶⁹ the Court interpreted the fourth prong of the *Central Hudson* analysis as meaning that the government need not employ the least restrictive means in regulating commercial speech, but rather one narrowly tailored to achieve the desired objective.⁷⁰

While there is no Supreme Court case squarely addressing whether labeling is commercial speech,⁷¹ it can be argued that it is commercial speech based on the similarities between labeling and advertising, which is the paradigm

⁶⁶*Youngs Drug*, 463 U.S. at 70, n. 20.

⁶⁷447 U.S. 557 (1980).

⁶⁸*Id.* at 566. This analysis has been central to subsequent commercial speech cases. See, e.g., *Metromedia, Inc. v. San Diego*, 453 U.S. 490 (1981); *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983); *Posadas de Puerto Rico Assocs. v. Tourism Company of Puerto Rico*, 478 U.S. 328 (1986).

⁶⁹492 U.S. 469 (1989).

⁷⁰*Id.* at 480.

⁷¹*Dunkelberger & Taylor*, *supra* note 37, at III A.

of commercial speech: both refer to a specific product, and... are motivated by the economic interest of the manufacturer.⁷² Some courts have accepted this analogy and have treated labeling as commercial speech,⁷³ and the FDA Compliance Policy Guide that deals with the seizure of books assumes without discussion that such books constitute commercial speech.⁷⁴ The combination of these facts has led some commentators to have no doubt that the Supreme Court would base a labeling case on the framework for analysis of governmental restrictions on commercial speech.⁷⁵

Assuming the Court does analyze labeling as commercial speech, it would then proceed with the four-step analysis outlined in *Central Hudson*. In the case of misbranding, the argument would have to focus on the issue of whether the book qualifies as misleading;⁷⁶ if it does, it receives no protection at all under the commercial speech doctrine, and FDA has free reign to prohibit it as it pleases. If the labeling is not misleading, it could constitutionally be regulated if the other three *Central Hudson* requirements are met.⁷⁷ However, in the

⁷²*Id.*

⁷³*See, e.g.,* Lever Bros. Co. v. Maurer, 712 F.Supp 645 (S.D. Ohio 1989); Adolph Coors Co. v. Bentsen, 944 F.2d 1543 (10th Cir. 1991).

⁷⁴FDA Compliance Policy Guide 7153.13 (Issued Dec. 1 1983; Revised Aug. 31, 1989).

⁷⁵Dunkelberger & Taylor, *supra* note 37, at III B.

⁷⁶Almost any writing that is not distilled to the simplest language possible, or is not comprehensive, can literally be misleading. *See, e.g.,* Beneficial Corporation v. FTC, 542 F.2d 611, 618 (3d Cir. 1976) (These consumers may well have been singularly dense. They were, nevertheless, a part of the audience to which the advertisements were directed); FTC v. Sterling Drug, Inc., 317 F.2d 669, 674 (2d Cir. 1963), quoting 1 Caliman, Unfair Competition and Trademarks S19.2(a)(1), at 341-44 (1950) (The general public has been defined as 'that vast multitude which includes the ignorant, and unthinking and the credulous, who in making purchases, do not stop to analyze but too often are governed by appearances and general impressions').

⁷⁷The Court would first ask whether the asserted governmental interest is substantial, and it would be very difficult to answer this in the negative in a food labeling case. Thus, the Court's true focus would likely be on the final two requirements: whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest. 447 U.S. at 566. This standard is clearly stricter than that employed in *Wall Street*, and a court employing it would thus be more likely to find that

case of misbranding, FDA currently would not have the statutory authority to do so, since the FD&C Act's misbranding provisions apply only to labeling that is false or misleading in any particular. Thus, if the labeling is not misleading, the rest of the *Central Hudson* analysis is moot in a misbranding case,⁷⁸ and treating labeling as commercial speech simply places a judicial seal of approval on any FDA action.

If FDA and the courts do not abuse common sense in designating labeling as misleading,⁷⁹ the effects of treating labeling as commercial speech appear to be desirable: FDA has enough power to protect consumers from devious merchants, and only fervent First Amendment zealots will decry a measure that prevents wholesale consumer fraud. However, despite this positive result, there is ample reason to doubt whether the Supreme Court should, or even could, classify labeling as commercial speech, as we will see in the next section.

C. Pure Speech

Ordinary, noncommercial speech is situated at the opposite end of the spectrum from the distinct category of regulated speech detailed in *Wall Street*. Pure speech is the kind of speech for which we presume the full weight of First Amendment protections, and for which restrictions are presumptively suspect unless they fit certain explicit criteria.

While the Supreme Court would likely categorize labeling as commercial speech, a regulation violated the First Amendment.

⁷⁸This would not be the case only if, for some reason, the FD&C Act's misleading in any particular is not coextensive with *Central Hudson*'s misleading.

⁷⁹The FD&C Act defines misleading in §201(n): [T]here shall be taken into account... not only representations made or suggested... but also the extent to which the labeling... fails to reveal [material] facts...

mercial speech,⁸⁰ it is important to emphasize that it is not certain that it would do so. While the analogy between advertising and labeling remains, the cases have been able to shed little light on *Central Hudson*, aside from standing as *ad hoc* subject-specific examples of what is permissible and what is not.⁸¹ This has led FDA to conclude that, unlike 'advertising pure and simple,' labeling does not fall clearly within the bounds of commercial speech.⁸² As we will see, there is nothing inherent in the nature of labeling that mandates its categorization as commercial speech, and it is unclear that it is desirable to do so.

Analyzing labeling as ordinary, noncommercial speech would allow FDA to protect consumers, while avoiding the myriad problems of the commercial speech doctrine. Alex Kozinski and Stuart Banner argue that the commercial/noncommercial distinction makes no sense,⁸³ an unsurprising fact considering that the Supreme Court plucked the commercial speech doctrine out of thin air.⁸⁴ Applying Kozinski and Banner's framework of analysis to the issue of labeling, one is led to conclude that treating labeling as ordinary speech would be preferable to treating it as commercial speech.

1.A Second Look at Commercial Speech: Problems With Classification and Justification

As mentioned previously, the Supreme Court has defined commer-

⁸⁰See *supra* section III B.

⁸¹Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech?*, 76 Va. L. Rev. 627, 631 (1990).

⁸²58 Fed. Reg. at 2525, *quoting* *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 637 (1985). FDA further argued, without substantiation, that labeling should certainly be considered closer to commercial speech than to 'pure' speech. *Id.* See also *SEC v. Wall Street Publishing Institute*, 851 F.2d 365, 372 (D.C. Cir. 1988) (we are not convinced that the feature articles [in a stock market magazine] under consideration here are commercial speech. The articles are not 'conceded' to be advertisements, and in fact, are not in advertisement format.)

⁸³*Id.* at 628.

⁸⁴*Id.*

cial speech as that which does no more than propose a commercial transaction.⁸⁵ Suppose an independent author writes *The Sweet Science*, a book that marvels over a plethora of unsubstantiated powers of honey. Does this book fall under the definition of commercial speech? Of course, by propose a commercial transaction, the Court cannot mean the proposal of a transaction to purchase the book itself, for if this were the case, every book and newspaper sold would be commercial speech. Instead, the Court must mean that the book needs to propose a transaction to purchase honey. One may argue that, if copies of the aforementioned tome are placed in a supermarket's honey aisle, they propose the following commercial transaction: Buy a jar of honey and reap the benefits described in this book. But the book merely reports the author's casual research, or general intuition, that honey will relieve what ails you; it does not exhort a consumer to do anything.⁸⁶

Even if the author of *The Sweet Science* secretly owns stock in a major honey corporation, and the book is part of an avaricious subterfuge to help him repay his law school loans, that should not result in the classification of the book's speech as commercial, since the commercial speech distinction cannot turn on the profit motive of the speaker; the labeling of speech as commercial has to be the result of an examination of the speech itself, not the speaker's

⁸⁵*Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 385 (1973). For another statement, see Thomas H. Jackson and John Calvin Jeffries, Jr., *Commercial Speech: Economic Due Process and the First Amendment*, 65 Va. L. Rev. 1 (1979) ('Commercial speech' refers to business advertising that does no more than solicit a commercial transaction or state information relevant thereto-).

⁸⁶Indeed, if the book is actually a hoax, one can imagine that the author will actually not want people to purchase honey. This way, it will take longer for people to discover that his claims are bogus.

purpose.⁸⁷ Otherwise, most books and newspapers, which are motivated at least in part by profit, would be considered commercial speech, and would be subject to its restricted protections.

Furthermore, even if one supposes that the book is explicit in urging readers to buy honey now or suffer grave consequences, why would the book suddenly not propose a commercial transaction when it no longer accompanies honey? For example, if *The Sweet Science* does no more than report that the dynamic combination of honey and cinnamon combats 27 of the most vexing ailments known to mankind,⁸⁸ and thereby does no more than propose a commercial transaction that readers buy the two nearby products, is the book more worthy of constitutional protection if it is moved to the next aisle? Assuming it would no longer be labeling under the FD&C Act, it would no longer be commercial speech.⁸⁹ It would be inconsistent and unnecessary to afford the same book different levels of constitutional protection depending upon what aisle in the supermarket it is found. Classifying labeling as a distinct category of regulated speech or as pure speech avoids this problem: no matter where in the supermarket the books are located, regulations limiting the sale of the books

⁸⁷Kozinski & Banner, *supra* note 81, at 640. See also *Virginia Pharmacy*, 425 U.S. at 761-665.

⁸⁸An article in a recent issue of the *WORLD NEWS* lists the following as conditions treatable with a simple mixture of honey and cinnamon: arthritis, hair loss, athlete's foot, bladder infections, toothache, canker sores, cholesterol, cold, infertility, upset stomach, gas, heart disease, high blood pressure, immune system, impotence, indigestion, influenza, longevity, pimples, poison ivy, skin infections, weight loss, cancer, fatigue, sore feet, bad breath, and hearing loss. Beatrice Dexter, *Cinnamon and Honey*, *WEEKLY WORLD NEWS*, January 17, 1995, at 8-9.

⁸⁹Nothing inherent about the book makes it commercial speech. If, for example, it were placed in a bookstore that does not sell food, it could hardly be said to be proposing a commercial transaction. If the book is advertising, it would still be commercial speech, but would be beyond the jurisdiction of both FDA and this paper.

would undergo the same constitutional scrutiny.⁹⁰

Another problem with squeezing labeling into the definition of commercial speech is the first phrase of the Supreme Court's definition of that category, no more. Suppose that the book under consideration also contains significant information on nonóhoney subjects such as the importance of Kant's philosophy and the use of correct grammar. Furthermore, suppose that the author ingeniously interweaves these subjects with his theory of the goodness of honey. The Court dealt with a similar issue in the *Fox* case. During a clearly commercial Tupperware Party that violated a New York statute by taking place in a SUNY dormitory, the salesmen discussed subjects such as how to be financially responsible and how to run an efficient home.⁹¹ The Court held that the speech was still commercial, since the commercial and noncommercial aspects were not inextricably intertwined: No law of man or of nature makes it impossible to sell housewares without teaching home economics, or to teach home economics without selling housewares.⁹²

The Court dismisses the issue with such ease in part because of its selective reading: in citing the standard *Virginia Pharmacy* definition of commercial speech, the *Fox* Court slyly omits the phrase no more than,⁹³ presumably to avoid the heart of the matter, which is that the doctrine of commercial speech rests on a clean distinction between the market for ideas and the market

⁹⁰Of course, since FDA pursues only the written material that is considered labeling, whether a misleading book accompanies the article it labels will still have an effect on FDA's decision to take action against it. However, the different treatment the books receive will be a matter of FDA policy, not a constitutional matter of the level of protection the speech should receive.

⁹¹492 U.S. at 474.

⁹²*Id.*

⁹³*Id.* at 473.

for goods and services.⁹⁴ In practice, this clean distinction is often illusory, especially when books are at issue: it is rare for an entire book to have nothing more to say than Buy honey. Thus, the classification of labeling as commercial speech would require the Court to dilute the commercial speech doctrine by engaging in Fox-like backpedaling.⁹⁵

Not only are there significant problems in defining labeling as commercial speech, but the two justifications for affording commercial speech less protection than noncommercial speech⁹⁶ do not apply well to labeling. The first justification is that the truth of commercial speech is more objective, and thus easier to ascertain, than noncommercial speech. But what about a book's claim that the power of honey is such that for years, arthritis sufferers have eased their pain with two teaspoons of honey per day? Is there an adequate way to verify this? Even if scientists did determine that nothing in the chemical composition of honey causes it to soothe pain, that would not be the end of the inquiry, since honey may have a powerful placebo effect. One can think of dozens of similar examples of statements that are difficult to verify. Thus, the determination of whether the claims of a book used as labeling are truthful can often be highly contestable.

In addition, every day we see false or misleading speech that is at least as verifiable as the above example: supermarket tabloid gossip and

⁹⁴Thomas H. Jackson & John Calvin Jeffries, Jr., *Commercial Speech: Economic Due Process and the First Amendment*, 65 Va. L. Rev. 1, 2(1979).

⁹⁵In his Central Hudson concurrence, Justice Stevens warned that it is important that the commercial speech doctrine not be defined too broadly lest speech deserving of greater constitutional protection be inadvertently suppressed. 447 U.S. at 579.

⁹⁶See *supra* section III B.

horoscopes are two common examples. Yet these forms of speech do not receive less protection than ordinary speech. We also see examples of speech that is paradigmatically objective, but receives full First Amendment protection: a person engaged in scientific speech can claim anything he wants about the effects of honey, without governmental intrusion.⁹⁷

Even if we were to grant that the claims in books used as labeling are objectively verifiable, it is unclear why that should result in less protection for such speech. Consumers are far less likely to be misled about matters they can check out by reference to objective facts than about such intangibles as the leadership qualities of a political candidate...⁹⁸ If an author's remedy proves to be ineffective, word will spread, and not many consumers will purchase his book, or the honey it eulogizes. The unfortunate people who have used the honey without benefit will discontinue their therapy and hopefully will be more wary next time.

The Supreme Court's second justification for treating commercial speech differently is that, since it is engaged in for profit, it is more durable and less likely to be chilled. But, if books making health claims are big business, then so are newspapers and movies,⁹⁹ but these are not treated as commercial speech. In addition, economic motivation is not the only strong interest behind speech, and there is no evidence that money is a more steady anchor for speech than religious or artistic concerns.¹⁰⁰

⁹⁷See Kozinski & Banner, *supra* note 81, at 635.

⁹⁸*Id.* at 636-637.

⁹⁹See *id.* at 637.

¹⁰⁰See *Id.*

2. Ramifications of Treating Labeling as Ordinary Speech

An initial reaction to the proposal that courts should treat labeling as ordinary speech might be that this would hamper FDA's ability to protect consumers, especially relative to classifying labeling in one of the two categories previously discussed. Will books that misbrand food be entitled to the same protection as Popeye cartoons that make outrageous claims about the power of spinach? Thankfully, no. If we treat labeling as ordinary speech, we fall back on [the] standard¹⁰¹ analysis espoused in *United States v. O'Brien*.¹⁰² [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.¹⁰³

In *O'Brien*, the Court applied this framework to determine that a law prohibiting the knowing mutilation of Selective Service certificates did not abridge freedom of speech.¹⁰⁴ While the facts of *O'Brien* do not resemble those of food labeling cases, the *O'Brien* test has gained immeasurable significance by influencing the resolution of first amendment problems reaching far beyond [its] original context.¹⁰⁵ The *O'Brien* framework has found use in balancing incidental restrictions of expression... content-neutral restrictions of fully pro-

¹⁰¹Kozinski & Banner, *supra* note 81, at 651.

¹⁰²391 U.S. 367 (1968).

¹⁰³*Id.* at 377.

¹⁰⁴*Id.*

¹⁰⁵Keith Werhan, *The O'Briening of Free Speech Methodology*, 19 *Ariz. St. L.J.* 635, 637 (1987).

tected expression... content-based restrictions of commercial speech... [and has] appeared increasingly as a framework for addressing other discrete first amendment problems arising in a variety of settings.¹⁰⁶ For example, in *Procunier v. Martinez*,¹⁰⁷ the Court used the analysis in deciding a case in which prisoners challenged regulations that allowed for the censorship of their mail. The Court determined that *O'Brien* was generally analogous to the issue at bar in *Procunier*, since in broader terms, both cases involved restrictions on First Amendment liberties by governmental action in furtherance of legitimate and substantial state interests other than suppression of expression.¹⁰⁸ The *O'Brien* analysis has also been used in contexts as diverse as a challenge to a governmental passive enforcement policy,¹⁰⁹ and restrictions placed on broadcasters by the Public Broadcasting Act.¹¹⁰

This presence of *O'Brien* balancing across a considerable landscape of free speech issues¹¹¹ demonstrates that treating labeling as noncommercial speech, despite dire predictions from some quarters, will not give free reign to unscrupulous salesmen.¹¹² FDA could easily justify the use of the misbranding provisions of the FD&C Act against books with an *O'Brien*-like analysis: preventing the misbranding of food furthers an important governmental interest, which is related to Americans' physical and financial well-being, not suppression of free expression. The restriction is no greater than necessary, since it

¹⁰⁶*Id.*

¹⁰⁷416 U.S. 396 (1974).

¹⁰⁸*Id.* at 411-412.

¹⁰⁹*Wayte v. United States*, 470 U.S. 598, 610-614 (1985).

¹¹⁰*FCC v. League of Women voters of California*, 468 U.S. 364, 378-384 (1984).

¹¹¹*Werhan*, *supra* note 105, at 638.

¹¹²*Rozinski & Banner*, *supra* note 81, at 651.

applies only to labeling, which means simply that the book cannot accompany the food it misleadingly touts. If, however, FDA's interpretation of the terms misleading or labeling were to expand, the Court could overturn FDA's decision to seize a book if the seizure was too attenuated to further an important governmental interest, or the restriction was greater than necessary. Thus, First Amendment concerns receive substantial protection under *O'Brien*, while FDA can adequately protect consumers.

In addition, the treatment of labeling as ordinary speech fits nicely into the widely held paradigm of when regulation is desirable: in general, the market should be left to itself, but when there is a market failure, it is legitimate to regulate. In the marketplace of labeling, preventing the inefficiency of consumer misinformation, i.e., misbranding, allows things to run more smoothly.

IV. Conclusion

The use of books with misleading claims as labeling flourishes in food and drug stores today, as a casual glance around such establishments will demonstrate. It is important for FDA to have effective means to enforce its mandate prohibiting misbranding, so that it can protect consumers who are credulous or desperate. However, it is also important to acknowledge the primacy of freedom of speech in our society, and the fact that, for any regulation on misbranding to be truly legitimate, it must account for the important First Amendment concerns that are implicated. Despite FDA's attempts at analogizing food labeling to the stock market, there is no convincing reason to classify food labeling as a distinct category of regulated speech. If we want to ensure

that First Amendment rights are not encroached, it is dangerous to grant the government power to regulate speech with only minimal scrutiny when this is not absolutely necessary. There is a stronger, but still not convincing reason to categorize labeling as commercial speech. Placing labeling squarely into the definition of commercial speech requires mental gymnastics, and the justifications for commercial speech do not stand up to analysis when applied in the context of labeling. Finally, the treatment of labeling as ordinary speech allows FDA to enforce its mandate to prevent misbranding, without threatening overregulation or relying on an ill-fitting doctrine. The importance of classifying labeling is a result of the tension between the two strong interests present, and the balancing test of *O'Brien* is a workable compromise, steering a middle course between the leanings for and against protection.¹¹³

¹¹³Werhan, *supra* note 105, at 671.