

# HEALTH RELATED CLAIMS, THE MARKET FOR INFORMATION, AND THE FIRST AMENDMENT

*J. Howard Beales III* <sup>†</sup>

Food and drug law is replete with restrictions on truthful commercial speech. Drug manufacturers must confine claims about the safety and efficacy of their products to those the Food and Drug Administration (FDA) has approved for labeling. Food manufacturers may discuss the relationship between diet and disease if the FDA has determined that there is “significant scientific agreement” that the claims are true. Pursuant to FDA guidance, manufacturers may also make more limited claims to consumers that there is evidence of a diet-disease relationship, but that such evidence does not rise to the requisite level of “significant scientific agreement” regarding the truth of the claim. Those who say too much, however, risk an FDA finding that they have made a “drug” claim, and are therefore illegally selling the food as an unapproved new drug. Other producers, who would like to inform consumers of a diet-health relationship, are often prohibited from doing so because their products have too much of some condemned nutrient. For example, the food producer cannot explain why the amount of saturated fat is significant, from a health perspective, in foods low in saturated fat (as defined by the FDA) but high in total fat content. Therefore, the high total fat content of the food prohibits this producer from making a health claim (e.g., “heart healthy—low in saturated fat”).

Most of these restrictions have their roots in regulatory approaches that were developed in an era when the Supreme Court held that commercial speech was not protected under the First Amendment at all.<sup>1</sup> Over time, the commercial speech doctrine developed and increasingly protected truthful speech from governmental restrictions that were founded on the notion that it would be better for consumers to remain ignorant. The FDA has tended to assume, however, that the doctrine does not really apply to health and safety claims.

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<sup>†</sup> Professor of Strategic Management and Public Policy, The George Washington School of Business. The author was Director of the FTC’s Bureau of Consumer Protection from 2001 to 2004.

<sup>1</sup> *Valentine v. Chrestensen*, 316 U.S. 52, 54 (1942).

A common metaphor in First Amendment analysis is the “marketplace of ideas.” If advocates of competing points of view can make their best case, free of government regulation, the best and most accurate ideas are most likely to prevail. From an economic perspective, the rationale for protecting commercial speech from undue governmental interference is the marketplace for information. Part I of this Article considers the market for information. Part II describes some issues in the commercial speech doctrine in light of the economics of the market for information. Part III then reviews the empirical evidence on the importance of the free flow of information in assuring competitive market outcomes. Finally, this Article offers some conclusions.

## I. THE MARKET FOR INFORMATION

Information is costly. There are costs of producing information, such as testing and research, and costs of disseminating information, such as through advertising or other channels. It costs consumers time and effort to process, understand, and use the information they obtain. Because information is costly, it would never be optimal for consumers to become fully informed. Instead, consumers must decide how much information to obtain. Rational consumers will seek additional information until the marginal benefits of the added information equal the marginal costs of obtaining that information.<sup>2</sup> Thus, as the cost of information increases, rational consumers will choose to obtain less information.

### A. Information and Market Equilibrium

Even with costly information, however, markets can produce competitive outcomes. Some consumers will be informed about price or product characteristics. As long as the group of consumers who seek out a particular item of information is large enough to be worth competing for, their search will police the marketplace.<sup>3</sup> Because sellers cannot easily discriminate between informed and uninformed consumers in most circumstances, they must offer a competitive price (or competitive terms on other product dimensions) if they wish to

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<sup>2</sup> See generally George J. Stigler, *The Economics of Information*, 69 J. POL. ECON. 213 (1961) (analyzing consumers' search for information and how the search impacts market price).

<sup>3</sup> See Alan Schwartz & Louis L. Wilde, *Intervening in Markets on the Basis of Imperfect Information: A Legal and Economic Analysis*, 127 U. PA L. REV. 630, 633-35 (1979).

compete for the informed buyers.<sup>4</sup> With enough informed buyers, the equilibrium outcome will be the competitive equilibrium, even though many buyers choose not to be informed.

Given the importance of the costs of obtaining information, government actions that reduce the cost of information can improve market performance. Standardized measuring systems that facilitate product comparisons, such as grading systems for meat, standardized measurements for fuel economy, or nutrition labels, can ease the consumer's task of obtaining information and enhance competition on the measured dimension.<sup>5</sup>

Although consumers produce a great deal of information as a result of their own shopping activities,<sup>6</sup> other sources of information are also readily available. Information is available for purchase from intermediaries such as Consumer Reports.<sup>7</sup> Consumers can also hire experts to assist them in finding the product or service that best fits their needs. They can obtain information from press articles or product reviews. Perhaps most important, they can use information that sellers provide through labels and advertisements—as long as the government is willing to permit them to do so. The substantial investments that most firms make in advertising are best understood as efforts to provide information to consumers. As George Stigler noted, advertising is “an immensely powerful instrument for the elimination of ignorance . . . .”<sup>8</sup>

### B. Seller-Provided Information

Seller incentives to provide positive information to consumers are obvious. Absent regulatory barriers, sellers will tell consumers about

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<sup>4</sup> Shopping occurs even for the terms of standard form contracts. See J. Howard Beales III & Timothy J. Muris, *The Foundations of Franchise Regulation: Issues and Evidence*, 2 J. CORP. FIN. 157, 163-166 (1995) (reporting evidence on shopping for standardized franchise contracts); see also James R. Barth, Joseph J. Cordes, & Anthony M.J. Yezer, *Benefits and Costs of Legal Restrictions on Personal Loan Markets*, 29 J.L. & ECON. 357, 357-380 (1986) (providing evidence of shopping for personal loan terms). The critical role of marginal consumers in determining the competitive market outcome is discussed in more detail in J. Howard Beales III, *Consumer Protection and Behavioral Economics: To BE or Not to BE?*, 4 COMPETITION POL'Y INT'L 149, 152-53 (2008).

<sup>5</sup> Howard Beales et al., *The Efficient Regulation of Consumer Information*, 24 J.L. & ECON. 491, 523 (1981).

<sup>6</sup> For example, consumers shopping for clothing can obtain information about such characteristics as price, style, color, and basic fabric composition simply by examining the product.

<sup>7</sup> See CONSUMER REPORTS, <http://www.consumerreports.org/cro/index.htm> (last visited February 15, 2011).

<sup>8</sup> Stigler, *supra* note 2, at 220.

product attributes that consumers desire. When regulatory barriers restrict the provision of truthful information, either explicitly or effectively, they are likely to reduce consumer welfare.

Sellers also have strong incentives to reveal negative information about products. Because the absence of a negative characteristic (or less of the characteristic than competing products) is a positive product benefit, sellers that look better on the negative characteristic have an incentive to reveal that fact. Fat, for example, is generally considered a negative attribute of a food.<sup>9</sup> Sellers of fat free products will inform consumers of that fact, creating an incentive for sellers of low fat products to identify themselves, which in turn creates an incentive for sellers that can only say “less fat” to provide information about fat content. If consumers who care about the characteristic assume that sellers who are silent have more of the undesirable characteristic than those who reveal, there is an incentive for all but the worst product on that dimension to disclose. Consumers will correctly assume that the producer who remains silent is the worst. Thus, the unfolding principle argues that sellers will voluntarily provide even negative product information, as long as competing products differ on the characteristic.<sup>10</sup>

There is clear evidence that the unfolding principle operates in practice, though it is less clear that disclosure is as complete as the theory would suggest. Economist Alan Mathios finds that before mandatory nutrition labeling, all low fat salad dressings disclosed fat content but high fat dressings did not.<sup>11</sup> FTC researchers Ippolito and Mathios also found nearly complete unfolding for ready to eat cereals, butter and margarine, but incomplete unfolding for frozen pizzas and cigarettes.<sup>12</sup>

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<sup>9</sup> For example, the USDA’s *Dietary Guidelines for Americans* recommends that Americans “reduce the intake of calories from solid fats and added sugars.” U.S. DEP’T AGRIC., EXECUTIVE SUMMARY 3 (2010), available at <http://www.mypyramid.gov/guidelines/ExecSumm.pdf>.

<sup>10</sup> See generally Sanford J. Grossman, *The Informational Role of Warranties and Private Disclosure about Product Quality*, 24 J. L. & ECON. 461 (1981) (developing the general theory that sellers may voluntarily provide good and bad product quality information); Paul H. Rubin, *The Economics of Regulating Deception*, 10 CATO J. 667, 680 (1991) (applying negative product-characteristic theory to advertising).

<sup>11</sup> Alan D. Mathios, *The Impact of Mandatory Disclosure Laws on Product Choices: An Analysis of the Salad Dressing Market*, 43 J.L. & ECON. 651, 660 (2000).

<sup>12</sup> Pauline M. Ippolito & Alan D. Mathios, *The Regulation of Science-Based Claims in Advertising*, 13 J. OF CONSUMER POL’Y 413, 413-45 (1990).

### C. Government Intervention

If information markets are to work efficiently, the information they provide must be accurate and reliable. Absent some check, a seller's incentive to overstate the advantages of its offering is straightforward. Intervention to prohibit false or deceptive claims is therefore essential.

Government intervention, however, is not the sole force for honesty in the marketplace. In some circumstances, market incentives alone are sufficient to assure that information is reliable. With search characteristics, which consumers can verify on their own prior to purchase, there is little risk of misleading claims.<sup>13</sup> There is simply no incentive to misrepresent such characteristics, because consumers will discover the truth prior to the purchase.

For experience characteristics,<sup>14</sup> which can only be determined by trying the product, there is more possibility that misleading claims will be profitable. For products that are inexpensive and frequently purchased, however, there is little difference between search and experience characteristics. The costs of a single trial are low, and seller profitability is likely to depend on repeat purchases.<sup>15</sup> Again, there is little incentive to engage in misleading claims, because such claims will not generate repeat purchases once consumers learn the truth.

In many circumstances, the mere fact that a firm advertises is a source of information about product quality. When sellers depend on repeat purchases, as they do in many consumer goods markets, they can signal their quality with investments in advertising.<sup>16</sup> These investments only yield a return if consumers continue to buy the product. Investments in advertising thus act as a bond, which the firm will lose if poor performance leads consumers to stop purchasing the product. Such investments are an important market incentive to ensure that firms provide what they promise.<sup>17</sup> Similarly, a seller's reputation is an intangible asset that is at risk from misleading practices, and provides an important incentive for honesty and fair dealing.<sup>18</sup>

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<sup>13</sup> The distinction between search and experience goods is due to Phillip Nelson. See Phillip Nelson, *Information and Consumer Behavior*, 78 J. POL. ECON. 311, 312-14 (1970).

<sup>14</sup> *Id.*

<sup>15</sup> See Phillip Nelson, *Advertising as Information*, 82 J. POL. ECON. 729, 730-31 (1974).

<sup>16</sup> *Id.* at 734.

<sup>17</sup> See Benjamin Klein & Keith B. Leffler, *The Role of Market Forces in Assuring Contractual Performance*, 89 J. POL. ECON. 615 (1981).

<sup>18</sup> Mark Armstrong, *Interactions between Competition and Consumer Policy*, 4 COMPETITION POL'Y INT'L 97, 100-107 (2008) (arguing that competition on its own

The need for enforcement action to police the marketplace is greatest with claims about credence characteristics.<sup>19</sup> Most health-related claims are credence claims, which cannot be fully evaluated even after purchase. As disagreements among experts make clear, consumers may find it difficult to evaluate claims about the quality of expert advice on whether a particular medical treatment was really necessary or appropriate, or whether the lack of heart disease was attributable to a diet high in oat bran.

## II. THE COMMERCIAL SPEECH DOCTRINE AND THE MARKET FOR INFORMATION

The Supreme Court's commercial speech jurisprudence allows government restrictions to ensure "that the stream of commercial information flow[s] cleanly as well as freely."<sup>20</sup> For this reason, the court has consistently held that misleading or deceptive speech is not protected by the First Amendment.<sup>21</sup>

This simple and straightforward proposition, however, conceals a difficult issue that the courts have yet to address in any systematic fashion: What does it mean to say that a communication is misleading or deceptive?

Virtually any communication is subject to misinterpretation. If enough recipients hear or read the message, some of them will likely take away a meaning that is something other than what the speaker intended. Moreover, that understanding of the message may be completely false. This inherent problem of communication is particularly problematic in the context of marketing messages, which are almost always brief and presented in times and places where consumers may not pay full attention. Marketers frequently devote significant resources to refining their advertising to ensure that it effectively conveys the intended message, but however straightforward the message and however careful the execution, some are likely to misinterpret it. In academic studies of brief communications, some aspect of both advertising and editorial content is misunderstood by 20 to 30 percent

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can often protect consumers); Paul H. Rubin, *Regulation of Information and Advertising*, 4 COMPETITION POL'Y INT'L 169, 175 (2008).

<sup>19</sup> See Michael R. Darby & Edi Karni, *Free Competition and the Optimal Amount of Fraud*, 16 J.L. & ECON. 67, 69 (1973).

<sup>20</sup> *Edenfield v. Fane*, 507 U.S. 761, 768 (1993) (quoting *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 772 (1976)).

<sup>21</sup> *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980).

of the audience.<sup>22</sup> If regulators insist on communications that cannot be misunderstood, the result is likely to be communications that are also uninformative.

In the past, the Federal Trade Commission (FTC) sought to insist on advertising that was clear enough that “wayfaring men, though fools” would not misunderstand.<sup>23</sup> This approach to deception evolved before either the economic or constitutional significance of the free flow of information was appreciated, and tended to restrict marketers’ ability to provide useful information to consumers. Under this impossible standard, the FTC challenged advertising for a “permanent” hair dye on the theory that consumers might think the product would color hair that had not yet grown out.<sup>24</sup> It challenged a one-volume desktop encyclopedia because it did not in fact contain “[e]verything you’ve ever wanted to know—on every conceivable subject.”<sup>25</sup> As recently as 1979, it contended that “every body needs milk” was deceptive because it included those who were allergic to milk, a claim that was ultimately rejected by the administrative law judge.<sup>26</sup> It was not until the Commission adopted its Deception Policy Statement in 1983 that it formally disavowed this line of cases.<sup>27</sup> The Policy Statement provides that only reasonable interpretations of advertising are actionable: an act or practice is only deceptive if it is likely to mislead consumers acting reasonably in the circumstances about a material issue.

The FTC’s “reasonable consumer” or “reasonable interpretation” standard is ultimately an empirical one, depending on how ordinary members of the intended audience interpret the message. In practice, actual copy tests are relatively infrequent because of resource consid-

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<sup>22</sup> See JACOB JACOBY ET AL., MISCOMPREHENSION OF TELEVISED COMMUNICATIONS 64 (1980) (noting the statistics of miscomprehension for television viewers). For print communications, see JACOB JACOBY & WAYNE D. HOYER, THE COMPREHENSION AND MISCOMPREHENSION OF PRINT COMMUNICATIONS (1987). Both studies compare advertisements with excerpts of editorial content designed to be roughly equal in length, and find no significant differences in the extent of miscomprehension.

<sup>23</sup> *Charles of the Ritz Distrib. Corp. v. FTC*, 143 F.2d 676, 680 (2d Cir. 1944); *General Motors Corp. v. FTC*, 114 F.2d 33, 36 (2d Cir. 1940).

<sup>24</sup> *Clairol, Inc.*, 33 F.T.C. 1450, 1457 (1941).

<sup>25</sup> *Nat’l Comm. for Educ.*, 39 F.T.C. 171, 178 (1944).

<sup>26</sup> *Cal. Milk Producers Advisory Bd.*, 94 F.T.C. 429, 443 (1979).

<sup>27</sup> See F.T.C. Policy Statement on Deception (1983), appended to *Cliffdale Assoc.*, 103 F.T.C.110, 174 (1984), available at <http://www.ftc.gov/bcp/policystmt/addecept.htm> (last visited Nov. 13, 2010). The evolution of FTC policy that led to the Policy Statement is discussed in more detail in J. HOWARD BEALES & TIMOTHY J. MURIS, STATE AND FEDERAL REGULATION OF NATIONAL ADVERTISING 20-27 (1993), and in J. Howard Beales III, *Brightening the Lines: The Use of Policy Statements at the Federal Trade Commission*, 72 ANTITRUST L.J. 1057 (2005).

erations, but they are often introduced in administrative litigation. The Commission has never set a bright line standard for the fraction of the audience that must receive a misleading message. Given the academic research on miscommunication, discussed above, 20 to 30 percent of the audience is likely to misunderstand in any event. Since the 1980s, the Commission has generally not pressed the envelope in the cases it has actually pursued.

Almost from the commercial speech doctrine's inception, disclosures have been constitutionally favored,<sup>28</sup> and sometimes required in preference to an outright ban on otherwise truthful speech.<sup>29</sup> Such requirements are often based on the notion that without added information, the message would be deceptive. Disclosure requirements are also adopted because regulators do not trust the unfolding process to provide sufficient information about negative product characteristics. Disclosure requirements are common in a number of fields, ranging from advertising regulation to food and drug regulation to securities regulation.<sup>30</sup>

Government attempts to increase the amount of information available to consumers may fail to achieve their objectives because of the negative reactions of consumers or sellers to these regulatory requirements. In fact, such requirements may reduce the amount of information that is effectively available to consumers. For consumers, additional information on a product label or in an advertisement may result in "information overload."<sup>31</sup> Adding more information will increase the cost of using that information because consumers must read and understand the entire message to find the items in which they are interested. If consumers decide that the information is not worth the effort, they may simply ignore the message. The result may be more information on the package (or in the advertisement), but less information actually received and understood by the consumer. Consumers may also misunderstand disclosed information, or draw incorrect inferences from the fact that the information is disclosed at all. For example, researchers found during an experiment that disclosing the yield

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<sup>28</sup> See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 637-38, 646 (1985); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976).

<sup>29</sup> *Pearson v. Shalala*, 164 F.3d 650, 659-60 (D.C. Cir. 1999).

<sup>30</sup> For a discussion of the limits of disclosure policies in a number of different contexts see Clifford Winston, *The Efficacy of Information Policy: A Review of Archon Fung, Mary Graham, and David Weil's Full Disclosure: The Perils and Promise of Transparency*, 46 J. ECON. LITERATURE 704, 706 (2008).

<sup>31</sup> See JOSEPH P. MULHOLLAND, SUMMARY REPORT ON THE FTC BEHAVIORAL ECONOMICS CONFERENCE (2007) available at <http://www.ftc.gov/be/consumerbehavior/docs/070914mulhollandrpt.pdf>.

spread premium that mortgage brokers earn reduced consumers' ability to identify the lowest cost mortgage.<sup>32</sup>

For sellers, disclosure requirements increase the cost of providing information that might trigger the requirement. Providing some information about one financing term (such as the interest rate or the monthly payment), for example, triggers a requirement to provide more complete information under the Truth in Lending Act.<sup>33</sup> Rather than face the added costs for advertising time or space, sellers may choose not to provide the triggering information.<sup>34</sup> Again, the result may be that consumers have less information than they did before the requirement. For example, an FTC requirement that advertisers disclose all material details of a warranty whenever any portion of the warranty is mentioned discouraged advertisers from promoting their warranties in advertising. Removal of the detailed disclosure requirements in 1985 offered the potential for more robust competition over warranty terms.<sup>35</sup>

Because of the costs of required disclosures, requiring excessive disclosure may be no different in practice than prohibiting truthful claims entirely. For example, the FDA's requirements for disclosures to accompany prescription drug advertising were written with advertising to physicians in mind.<sup>36</sup> They required the advertisement to include a so-called "brief summary" of prescribing information, amounting to roughly half of a page of fine print in a medical journal advertisement. When pharmaceutical manufacturers became interested in advertising on television directly to consumers, this requirement effectively prohibited advertising. Although the FDA has relaxed its policy to permit direct to consumer advertising, it has never revised the underlying regulations.<sup>37</sup> The impact of DTC advertising is discussed in more detail in the next section.

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<sup>32</sup> JAMES M. LACKO & JANIS K. PAPPALARDO, THE EFFECT OF MORTGAGE BROKER COMPENSATION DISCLOSURES ON CONSUMERS AND COMPETITION: A CONTROLLED EXPERIMENT 49 (2004) available at <http://www.ftc.gov/os/2004/01/030123mortgagefullrpt.pdf>.

<sup>33</sup> See, e.g., 12 C.F.R. § 226.16 (2010).

<sup>34</sup> See Beales et al., *supra* note 5, at 527-28 (explaining that in a mandatory disclosure scheme, providing certain information or making certain claims may "trigger" the requirement to provide additional information, which may discourage certain sellers from providing the triggering information).

<sup>35</sup> BEALES & MURIS, *supra* note 27, at 36.

<sup>36</sup> Michael S. Wilkes et al., *Direct-to-Consumer Prescription Drug Advertising: Trends, Impact, and Implications*, 19 HEALTH AFFAIRS 110, 113 (2000).

<sup>37</sup> See Margaret Gilhooley, *Heal the Damage: Prescription Drug Consumer Advertisements and Relative Choices*, 38 J. HEALTH L. 1, 17-18 (2005). Rather than revise the rules, the FDA issued a Guidance Document that allowed broadcast adver-

### III. ADVERTISING AND MARKET PERFORMANCE

#### A. Advertising and Price

Much of what we know empirically about the impact of advertising on market competition and consumer welfare arises from studies of restrictions on advertising in the United States. Prior to the extension of First Amendment protections to commercial speech, the restrictions studied were relatively crude. They often involved complete prohibitions on advertising sought by professional groups to limit competition among their members and thereby raise prices. For example, one of the earliest studies examined state prohibitions on eyeglasses advertisements. It found that prices were approximately 25 percent higher in states that prohibited advertising, as compared to states that permitted advertising.<sup>38</sup> Similarly, states that regulated advertising of the retail prices of prescription drugs had higher prices.<sup>39</sup>

Subsequent restrictions on advertising were more subtle, but still had adverse effects on market performance. For example, attorney advertising restrictions varied considerably. Some states restricted broadcast advertising, while others prohibited the use of pictures and required advertisements to be “dignified.”<sup>40</sup> States with more restrictions on advertising had higher prices for routine legal services.<sup>41</sup> Restricting types of media where advertising is otherwise permitted also leads to higher prices. The ban on broadcast advertising of cigarettes, for example, increased cigarette prices.<sup>42</sup>

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tising without including the brief summary. *See* Guidance for Industry on Consumer-Directed Broadcast Advertisements, 64 Fed. Reg. 43,197, 43,197-98 (Aug. 9, 1999).

<sup>38</sup> Lee Benham, *The Effect of Advertising on the Price of Eyeglasses*, 15 J. L. & ECON. 337, 344 (1972). A number of other studies of markets for eyeglasses and optometric services have reached similar conclusions. *See, e.g.*, Deborah Haas-Wilson, *The Effect of Commercial Practice Restrictions: The Case of Optometry*, 29 J. L. & ECON. 165, 182 (1986) (finding that “media advertising by optometrists is associated with lower prices”); John E. Kwoka, Jr., *Advertising and the Price and Quality of Optometric Services*, 74 AM. ECON. R. 211, 216 (1984).

<sup>39</sup> JOHN F. CADY, RESTRICTED ADVERTISING AND COMPETITION: THE CASE OF RETAIL DRUGS 11, 20 (1976).

<sup>40</sup> Attorney advertising restrictions in place at the time of these studies are described in WILLIAM W. JACOBS ET AL., IMPROVING CONSUMER ACCESS TO LEGAL SERVICES: THE CASE FOR REMOVING RESTRICTIONS ON TRUTHFUL ADVERTISING (1984).

<sup>41</sup> John R. Schroeter, Scott L. Smith & Steven R. Cox, *Advertising and Competition in Routine Legal Service Markets: An Empirical Investigation*, 36 J. INDUS. ECON. 49, 59 (1987).

<sup>42</sup> Robert F. Porter, *The Impact of Government Policy on the U.S. Cigarette Industry*, in EMPIRICAL APPROACHES TO CONSUMER PROTECTION ECONOMICS 447, 459 (Pauline M. Ippolito & David T. Scheffmann eds., 1986).

Even advertising directed at children has been found to reduce prices. The introduction of television toy advertising was associated with significant price declines. When advertising was introduced in a particular city, prices fell; when advertising was withdrawn, they increased again. Similarly, cities where advertising was occurring had lower toy prices than cities where no advertising was present.<sup>43</sup> Similarly, Quebec's ban on television advertising to children has been found to raise the price of children's cereals in Quebec, compared to other provinces. Prices for adult or family cereals, however, which could still advertise, were no higher in Quebec than elsewhere.<sup>44</sup>

The price effects of advertising do not appear to depend on whether advertisements actually include price information. Price advertising has been found to lower prices in studies of retail gasoline markets,<sup>45</sup> prescription drugs, and retail liquor stores.<sup>46</sup> Restrictions are also associated with higher prices even where advertising rarely, if ever, includes price information, as in the studies of cereals, toys, and cigarettes discussed above. Thus, the critical factor appears to be the general competitive effects of advertising, rather than the specific effects of advertising price.

#### B. Health Claim Regulation and the Market for Information

Regulations on health-related claims for foods provide another source of data for those studying the impact of advertising regulations on the market. Such claims discuss the health effects of maintaining diets high or low in particular nutrients. For example, sellers have advertised the relationships between dietary saturated fat and serum cholesterol, as well as calcium and osteoporosis.<sup>47</sup>

While information in food advertising is regulated by the FTC, food labeling is regulated by the FDA. The FTC's approach to health claims in advertising has always permitted such claims if they were adequately substantiated. In contrast, the FDA regarded any label claim about the relationship between diet and disease as a drug claim until the late 1980s. Unless a seller wished to file for approval as a

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<sup>43</sup> Robert L. Steiner, *Does Advertising Lower Consumer Prices?*, J. MARKETING, Oct. 1973, at 21, 21-26.

<sup>44</sup> C. Robert Clark, *Advertising Restrictions and Competition in the Children's Breakfast Cereal Industry*, 50 J. L. & ECON. 757, 759-60 (2007).

<sup>45</sup> See ALEX MAURIZI & THOM KELLY, PRICES AND CONSUMER INFORMATION: THE BENEFITS FROM POSTING RETAIL GASOLINE PRICES (1978).

<sup>46</sup> Jeffrey Milyo & Joel Waldfogel, *The Effect of Price Advertising on Prices: Evidence in the Wake of 44 Liquormart*, 89 AM. ECON. REV. 1081 (1999).

<sup>47</sup> See PAULINE IPPOLITO & JANIS PAPPALARDO, ADVERTISING NUTRITION & HEALTH: EVIDENCE FROM FOOD ADVERTISING 1977-1997 E-8 to -11 (2002) (providing detailed data on the incidence of various health claims).

drug, such claims were illegal. In the 1960s, for example, FDA seized packages of Quaker Oatmeal as a misbranded drug, because the label discussed the relationship between fiber and serum cholesterol. Although some health claims were made in advertising, they were relatively infrequent until claims were also permitted on food labels.<sup>48</sup>

Change in the regulatory environment began with an act of civil disobedience. In 1984, Kellogg developed a marketing campaign for its high fiber All Bran cereal built around the recommendation of the National Cancer Institute that diets higher in fiber could reduce the risk of some kinds of cancer. Although the campaign was in clear violation of existing FDA regulations, it was developed in conjunction with the National Cancer Institute—a different part of the Department of Health and Human Services. FDA declined to take action, and in 1987 it proposed a rule change (later withdrawn) that would have permitted any health claim that was truthful and not misleading. Health claims—statements about the specific health effects of nutrients or foods—rose from approximately 2–4 % of food advertising in magazines to a peak of just over 11% of such advertising in 1989.<sup>49</sup> In response, Congress passed the Nutrition Labeling and Education Act of 1990,<sup>50</sup> which authorized health claims, but only with prior FDA approval of the content. The changing rules governing these health claims have provided a rich environment for studies on the impact of the content of seller-provided information on markets, as well as the impact of regulations on seller incentives to discuss certain product attributes.

Studies of the impact of claims about the relationship between fiber and cancer, which launched the health claims era, found a significant market response. The advertising messages led to an increase in

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<sup>48</sup> See John E. Calfee & Janis K. Pappalardo, *Public Policy Issues in Health Claims for Foods*, 10 J. PUB. POL'Y & MKTG. 33, 36 (1991) (discussing the early history of regulation of health claims); see also IPPOLITO & PAPPALARDO, *supra* note 47, at E-11 to -13 (providing key dates for later regulatory developments). The 1990 statute and its proposed implementing rules are discussed in BEALES & MURIS, *supra* note 27. The reconciliation of advertising and labeling rules is discussed in J. Howard Beales, *Regulatory Consistency and Common Sense: FTC Policy Toward Food Advertising Under Revised Labeling Regulations*, 14 J. OF PUB. POL'Y AND MARKETING 154, 154-56 (1995).

<sup>49</sup> IPPOLITO & PAPPALARDO, *supra* note 47, at E-8. The study is based on a content analysis of more than 11,000 food advertisements from 1977 through 1997. The sample consisted of all food advertisements that appeared in five leading women's magazines and three of the most popular general readership magazines. Magazine advertising is the second largest category of food advertising in the US. *Id.* at E-2.

<sup>50</sup> Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

fiber consumption. In part, the increase was the result of changes in purchasing patterns, but it was also a result of product changes. Although the weighted average fiber content of breakfast cereals had been essentially constant for several years preceding the introduction of the health claims, there was a positive and significant trend toward increasing fiber after the advertising began. There was no significant trend in fat or sodium content; the product improvements on the fiber dimension were not at the expense of deterioration on other aspects of nutrition. Interestingly, the increases in fiber consumption were greatest for the most disadvantaged groups. Although fiber consumption increased for all demographic groups, it increased more among racial minorities and female-headed households.<sup>51</sup>

One particularly common health claim concerned the relationship between diet and heart disease or serum cholesterol. Until 1984, such claims appeared in under 2% of magazine food advertising. After health claims began in earnest, they rose to appear in just over 8% of advertising in 1989.<sup>52</sup> Most of these claims concerned the relationship between fat, particularly saturated fat, and heart disease risk. Again, the increase in advertising claims was accompanied by significant consumption changes. Although fat and saturated fat consumption declined slightly between 1977 and 1985, both measures fell far more sharply between 1985 and 1990.<sup>53</sup> Again, information provided through advertising had a significant impact on the marketplace.

The Nutrition Labeling and Education Act of 1990 brought significant changes to the regulatory environment for health claims. Under the statute and its implementing regulations, which became effective in 1993 (for health claims) and 1994 (for nutrient content claims), health claims were only permitted after prior FDA approval of the substance of the claim.<sup>54</sup> Because the regulations authorize certain

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<sup>51</sup> PAULINE M. IPPOLITO & ALAN D. MATHIOS, FED. TRADE COMM'N, HEALTH CLAIMS IN ADVERTISING AND LABELING: A STUDY OF THE CEREAL MARKET, ix-xx (1989); Pauline M. Ippolito & Alan D. Mathios, *Information, Advertising and Health Choices: A Study of the Cereal Market*, 21 RAND J. ECON. 459, 473-74 (1990).

<sup>52</sup> IPPOLITO & PAPPALARDO, *supra* note 47, at E-10 to -11.

<sup>53</sup> Pauline M. Ippolito and Alan D. Mathios, *Information and Advertising: The Case of Fat Consumption in the United States*, 85 AM. ECON. REV. 91, 92 (1995); PAULINE M. IPPOLITO & ALAN D. MATHIOS, FTC, INFORMATION AND ADVERTISING POLICY: A STUDY OF FAT AND CHOLESTEROL CONSUMPTION IN THE UNITED STATES, 1977-1990 242 (1996).

<sup>54</sup> See 21 C.F.R. § 101.14 (2010). The FDA's initial rule implementing the statute proposed health claims concerning calcium and osteoporosis, dietary fiber and cancer, sodium and hypertension, lipids and heart disease, lipids and cancer, dietary fiber and heart disease, folic acid and neural tube defects, antioxidant vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart

health claims to include detailed information about the particular relationship and its significance,<sup>55</sup> many companies apparently believed both must be included in the claim.<sup>56</sup> Moreover, the rules sometimes require lengthy “model claims”<sup>57</sup> composed by the FDA and additional information about the relationship.<sup>58</sup> The rules also prohibit claims for certain products with “bad” nutrition profiles. For example, high fat products were no longer permitted to make claims about the relationship between fat composition and heart disease.<sup>59</sup>

These changes resulted in substantial declines in the incidence of health claims in advertising. From the peak of just over 11% of magazine food advertisements making some health claim in 1989, health claims fell to under 3% of advertisements in 1992–1994. Claims about heart disease and serum cholesterol were most dramatically affected, falling from 8.2% of all advertising in 1989 to zero in 1994.<sup>60</sup> A significant part of the decline was apparently due to the belief that claims were required to include the entire, burdensome model claims. When FDA proposed in 1995 to clarify that the full amount of information was not required (and the FTC clarified the relationship between the labeling rules and advertising in 1994), health claims again began to increase. By 1997, the end of the sample period, health claims again appeared in 8% of ads, and heart and serum cholesterol claims had returned to just under 4%.<sup>61</sup>

Undoubtedly, the category most affected by the new rules was advertising for fats and oils. In 1988 and again in 1990, 45% of all advertising for fats and oils included a disease-related claim. These claims provided information about the importance of fat composition, particularly saturated fats, to the risk of heart disease. But by 1994, these claims had entirely disappeared from advertising for fats and oils, as the regulations required.<sup>62</sup>

With less ability to explain to consumers why fat composition mattered, there was also less incentive for fats and oils manufacturers

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disease. BEALES & MURIS, *supra* note 27, at 50 n.16. Subsequent petitions have led to authorization for a number of additional claims.

<sup>55</sup> See, e.g., 21 C.F.R. § 101.75(a) (demonstrating the relationship between saturated fat and heart disease); *id.* § 101.75(b) (explaining the significance of the relationship).

<sup>56</sup> IPPOLITO & PAPPALARDO, *supra* note 47, at 100.

<sup>57</sup> See, e.g., 21 C.F.R. § 101.77(e) (model claims for relationship between soluble fiber and heart disease).

<sup>58</sup> See, e.g., *id.* § 101.77(c).

<sup>59</sup> *Id.* § 101.75(c)(2).

<sup>60</sup> See IPPOLITO & PAPPALARDO, *supra* note 47, at E-10.

<sup>61</sup> *Id.* at E-8 to -10.

<sup>62</sup> *Id.* at E-26 to -27.

to discuss fat composition at all. The total number of advertisements for fats and oils declined, as did the number of advertisements that included saturated fat content information. From a peak of twenty advertisements discussing saturated fat in 1992, the number of advertisements fell to only one in 1997.<sup>63</sup> Moreover, there is limited evidence that the shift in the informational content of advertising resulted in changes in the marketplace. With less information about both saturated fat content and its importance to health, consumer choices shifted toward cooking oils with more saturated fat and less monounsaturated fat.<sup>64</sup>

Requirements for specific disclosures to accompany claims often create particularly heavy burdens for comparative advertising claims, simply because there is often more that can be disclosed—the number describing the advertised product, the competitive product, and the absolute or comparative difference in the measurement. Although always useful, and arguably necessary to prevent deception in some circumstances, it is very difficult to argue that a truthful comparison is always misleading in the absence of this full set of information. Nonetheless, the food labeling regulations generally require more information to accompany comparative claims about nutrient content, even though such claims are particularly likely to facilitate consumer choice. With the exception of comparative claims about total fat content, comparative claims generally declined in frequency after the rules took effect.<sup>65</sup>

One such example is claims about calorie content and calorie comparisons. Part of the theory of the regulatory changes was that if consumers just focused on fat, calories would take care of themselves, because fat is so high in calories. Thus, the regulations made claims about fat content relatively easy, and claims about total fat content increased after the rule. Calorie and diet claims, however, decreased, falling from a peak of 22.5% of all food advertisements in 1991 to 12% in 1997. Comparative calorie claims, subject to further disclosure requirements, fell even more, from a peak of 11.2% of ads in 1989 to a low of 1.2% in 1995.<sup>66</sup> The FDA succeeded in shifting the focus from calories to fat, but the increase in obesity since 1990 certainly raises questions about whether that was really an improvement.

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<sup>63</sup> *Id.* at E-28.

<sup>64</sup> Alan D. Mathios, *The Importance of Nutrition Labeling and Health Claim Regulation on Product Choice: An Analysis of the Cooking Oils Market*, 27 AGRIC. & RESOURCE ECON. REV. 159 (1998).

<sup>65</sup> See IPPOLITO & PAPPALARDO, *supra* note 47, at E-6.

<sup>66</sup> *Id.* at 188 (Table B-1) (explaining that comparative calorie claims rebounded slightly, to 3.4% of ads in 1997).

The paradoxical effect of the changes in the rules governing health claims was that an effort to fine tune the information available to consumers resulted in the provision of less information about important product characteristics. Each individual claim that appeared may have been more complete and informative, but the aggregate number of health claims decreased because sellers wished to avoid the new regulatory burdens. Advertising claims about relevant health characteristics of products generally became less common. The prominent exception was claims about total fat content. Although prohibited for certain products, total fat claims were less burdened than other claims, and their frequency increased after the regulations took effect.<sup>67</sup>

The health claims experience makes clear that sellers have important incentives to provide information in competitive markets, even when the information is “bad.” That information has consequences in the marketplace, affecting both consumer choices and the nature of product offerings. The intense competition in the fats and oils category based on fat composition, for example, is easy to understand from the perspective of the economics of information. For consumers interested in changing the fat composition of their diet, the place to start is with fats and oils, not with products that have little fat in the first place.<sup>68</sup> Sellers have an incentive to compete for the business of such consumers, in part by providing relevant information.

Recently, the FDA has demonstrated a renewed interest in health claims, featuring a return to its pre-1984 position that health claims could convert a food into an unapproved new drug. In 2009, it issued a warning letter challenging Cheerios packaging claims that “you can Lower Your Cholesterol 4% in 6 weeks,” and that “Cheerios is . . . clinically proven to lower cholesterol.”<sup>69</sup> The package also included an FDA-approved health claim about the relationship between soluble fiber and the reduced risk of coronary heart disease, but the FDA took care to argue that the challenged cholesterol claims were “presented as separate, stand-alone claims through their location on the package and

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<sup>67</sup> *Id.* at E-4.

<sup>68</sup> Indeed, when the FDA subsequently proposed to require labeling of trans fat content, it relied in part on a cost benefit analysis indicating that it was fat composition, not total fat content of the diet, that influenced heart disease risk. *See* Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 64 Fed. Reg. 62,746, 62,763 (Nov. 17, 1999) (codified at 21 C.F.R. pt 101).

<sup>69</sup> Warning Letter from Charles Becoat, Dist. Dir., U.S. FDA, to Ken Powell, CEO, General Mills (May 5, 2009), *available at* <http://www.fda.gov/iceci/enforcementactions/warningletters/ucm162943.htm>.

other label design features.”<sup>70</sup> FDA’s approach is inconsistent with the long-established approach to advertising interpretation, which recognizes the need to examine “[t]he entire mosaic . . . rather than each tile separately.”<sup>71</sup> Instead, the FDA divided the label into its component tiles, distinguishing the “health claim” tile that it permits from the “drug claim” tile that is prohibited.

It is difficult to see how this challenge can withstand First Amendment scrutiny. FDA alleges that the claims are “drug claims,” but it does not allege that they are misleading. Absent the specific quantitative information and the reference to clinical trials that apparently converts Cheerios into a drug, it seems far more likely that consumers would overestimate the significance of fiber in reducing cholesterol, rather than underestimating the importance of the relationship that FDA agrees exists. The added information would appear to enhance consumer understanding, not reduce it. From the perspective of the market for information, this is the kind of seller-provided information that policy should seek to encourage, not prevent. The First Amendment should do the same.

Nor is it clear how the restriction can survive as a valid restriction on truthful commercial speech under the test the Supreme Court first articulated in *Central Hudson*. Under the *Central Hudson* test, the restriction must directly advance a substantial governmental interest and be no more restrictive than necessary.<sup>72</sup> Although there is undoubtedly a governmental interest in protecting public health through the drug approval process, preventing the possibility that the next Lipitor will come to market cleverly disguised as a breakfast cereal does little to advance that interest. The drug approval process seeks to prevent serious risks from potential side effects that can be fatal. There is simply nothing akin to these risks in the choice of which cereal to eat. The drug approval process might also be defended based on the need to prevent ineffective treatments, which might lead consumers to forego effective alternative therapies. With foods, however, there is simply no evidence that consumers rely on dietary changes in preference to medical treatment for the kinds of conditions that have been the subject of health claims. Breakfast choices simply do not pose the kinds of risks that the drug approval process seeks to prevent—

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<sup>70</sup> *Id.*

<sup>71</sup> *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963).

<sup>72</sup> *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980). Although the Court has become more protective of truthful commercial speech over time, it has continued to employ the *Central Hudson* test. *See, e.g.*, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367-68 (2002).

particularly when it is conceded that the soluble fiber in oats will indeed reduce serum cholesterol.

More fundamentally, the drug approval process itself poses challenges for a First Amendment analysis. Requiring prior approval before a product is marketed does not implicate First Amendment values, but much of what the FDA does under the authority of the approval process goes considerably beyond that. The process determines not only what can be sold, but also what can be *said* about products the government allows into the marketplace. This is commercial speech, and there is logically room for a great deal of speech that is truthful and not misleading, but beyond the confines of the FDA-approved labeling. Because a product is approved for a particular indication, there is a connection between speech and the process of deciding whether a drug provides benefits sufficient to justify the risks it may impose. An FDA concerned about protecting the drug approval process should seek to narrow its restrictions on truthful speech to those that are essential complements of the approval process. It is difficult to see how restricting truthful claims about Cheerios protects the integrity of the process in any meaningful way. Absent such a connection, however, the restriction is not “a means narrowly tailored to achieve the desired objective.”<sup>73</sup>

### C. Advertising and Prescription Drugs

Although direct to consumer (DTC) advertising has grown substantially in recent years, most promotional spending for drugs is still directed to physicians.<sup>74</sup> From its inception, the practice has been controversial, and has been banned in most other countries.<sup>75</sup> That controversy increased considerably in the wake of the Vioxx recall, a drug that had been heavily promoted through DTC advertising. In-

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<sup>73</sup> Bd. of Trs. of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 480 (1989).

<sup>74</sup> One study estimated that DTC advertising accounted for approximately 14% of total promotional expenditures for prescription drugs in 2005. Julie M. Donohue, et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 675 (2007); see also Cong. Budget Office, *Promotional Spending for Prescription Drugs*, 2 & n.2 (Dec. 2, 2009) available at [http://www.cbo.gov/ftpdocs/105xx/doc10522/12-02-DrugPromo\\_Brief.pdf](http://www.cbo.gov/ftpdocs/105xx/doc10522/12-02-DrugPromo_Brief.pdf) (estimating that DTC advertising accounted for just over 20% of promotional expenditures in 2008, but unlike Donohue et al., did not include the value of free samples in its measurements).

<sup>75</sup> See R.L. Kravitz & R.A. Bell, *Direct-to-Consumer Advertising of Prescription Drugs: Balancing Benefits and Risks, and a Way Forward*, 82 CLINICAL PHARMACOLOGY & THERAPEUTICS 360, 360 (2007).

deed, the recall led to proposals to ban DTC advertising or to delay its use until a drug had been on the market for some period of time.<sup>76</sup>

A number of surveys of patient and physician attitudes toward DTC advertising have been conducted,<sup>77</sup> but survey responses may not reflect the actual behavior of either group. Better evidence of the impact of advertising comes from studies relying on market data and actual behavior in the marketplace. DTC advertising is used for a relatively small number of drugs. Based on data from 1996–1999, advertising to consumers was more likely for new drugs, for more important drugs (those that receive priority reviews), and for under-treated diseases with large numbers of potential patients.<sup>78</sup> Because consumers may not seek treatment if they are unaware that an effective therapy exists, they may particularly benefit from learning about drug treatments. Thus, advertising is more likely for precisely the types of products that consumers are most likely to benefit from learning about—important new drugs for under-treated conditions.

There is evidence that DTC advertising may lead to increased treatment. A study across drug classes found that DTC advertising increased physician visits, with every twenty-eight dollars of DTC advertising resulting in one additional visit in which a drug is prescribed within twelve months.<sup>79</sup> Other studies have examined advertising in particular drug markets, with several studies examining the marketing of a class of drugs that reduce cholesterol, collectively known as statins. The first study of this market, using aggregate data, found small or insignificant effects of advertising on the total number of prescriptions for statins.<sup>80</sup> Subsequent studies using more disaggregated data, however, have found significant effects. A widespread concern about many drug therapies is that patients may not take their medicine as regularly as they should. It is therefore noteworthy that DTC statin advertising appears to increase compliance with a prescribed regime. Moreover, advertising for one brand increases com-

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<sup>76</sup> See David C. Vladeck, *The Difficult Case of Direct-To-Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259, 278 (2007).

<sup>77</sup> See generally JE Calfee, *An Assessment of Direct-to-Consumer Advertising of Prescription Drugs*, 82 CLINICAL PHARMACOLOGY & THERAPEUTICS 357 (2007) (describing surveys of consumers and physicians).

<sup>78</sup> Toshiaki Iizuka, *What Explains the Use of Direct-to-Consumer Advertising of Prescription Drugs?*, 52 J. INDUS. ECON. 349, 373 (2004).

<sup>79</sup> Toshiaki Iizuka & Ginger Zhe Jin, *The Effect of Prescription Drug Advertising on Doctor Visits*, 14 J. ECON. & MGMT. STRATEGY 701, 703 (2005) (analyzing a sample of 151 drug classes over seventy-two months, from 1994–2000).

<sup>80</sup> John E. Calfee et al., *Direct-to-Consumer Advertising and the Demand for Cholesterol-Reducing Drugs*, 45 J.L. & ECON. 673, 680–81 (2002).

pliance for patients using competing products as well.<sup>81</sup> Some of the increase in compliance may occur because patients are more involved in the decision about their therapy when there is more advertising, and some may occur because the advertising reminds patients to take their medicine. Higher levels of statin television advertising were also associated with improvement in the likelihood of attaining cholesterol management goals, particularly for patients with the least restrictive goals.<sup>82</sup> This result is consistent with improved compliance as a result of DTC advertising.<sup>83</sup>

Other studies have examined the market for antidepressants, which have also been extensively advertised. A study using insurance claims data found that patients diagnosed with depression during periods when DTC advertising was high were more likely to initiate medication therapy, an effect that was not present for detailing or free samples. DTC advertising was also associated with an increase in the number of patients who received the appropriate duration of therapy.<sup>84</sup> Another study, using survey data on medical expenditures, also found that advertising increased the likelihood that consumers would initiate antidepressant therapy, but did not increase utilization among those already taking the medications. As the authors noted, “this is consistent with a promotional campaign that seems to alert consumers to the product’s existence.”<sup>85</sup>

Although there have certainly been fears that DTC advertising might result in inappropriate prescribing, there does not appear to be systematic, market-based evidence to support that fear. A controlled trial of antidepressant prescribing used actors pretending to be suffering from either major depression or adjustment disorder. The authors viewed an antidepressant prescription as appropriate in the first condition, but not in the second. The actors either requested a specific drug, requested a drug treatment generally, or made no request. Among

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<sup>81</sup> Marta Wosinska, *Direct-to-Consumer Advertising and Drug Therapy Compliance*, 42 J. MARKETING RES. 323, 324 (2005).

<sup>82</sup> W. David Bradford et al., *Effects of Direct-to-Consumer Advertising of Hydroxymethylglutaryl Coenzyme A Reductase Inhibitors on Attainment of LDL-C Goals*, 28 CLINICAL THERAPEUTICS 2105, 2105, 2116 (2006).

<sup>83</sup> See Olivier Armandier & Soiliou Namoro, *Prescription Drug Advertising and Patient Compliance: A Physician Agency Approach*, 6 ADVANCES ECON. ANALYSIS & POL’Y 1545 (2006) (finding that improved compliance has also been reported for glaucoma medications).

<sup>84</sup> Julie M. Donohue et al., *Effects of Pharmaceutical Promotion on Adherence to the Treatment Guidelines for Depression*, 42 MED. CARE 1176, 1179-80 (2004).

<sup>85</sup> Chad D. Meyerhoefer & Samuel H. Zuvekas, *The Shape of Demand: What Does It Tell Us about Direct-to-Consumer Marketing of Antidepressants?*, 8 B.E. J. ECON. ANALYSIS & POL’Y, no. 2, 2008, at 1.

patients with major depression who requested a drug generally, 98% received “minimally acceptable initial care,” compared to 90% who asked for a specific drug and only 56% of those who made no drug request. Patients with adjustment disorder, for whom a prescription was less clearly warranted, were also more likely to receive a drug in response to a specific or general request, which may suggest some over prescribing in this case.<sup>86</sup>

Studies have also examined the promotion of COX-2 inhibitors such as Vioxx. One study found consistent and statistically significant effects of advertising on the number of osteoarthritis patient visits,<sup>87</sup> suggesting that the advertising led to treatment for patients who would not otherwise have received it. A separate study by several of the same authors found that increased Vioxx advertising was associated with reduced wait times between diagnosis and the beginning of treatment, although Celebrex advertising was associated with longer delays. Moreover, patients who were better candidates for COX-2 inhibitor therapy had shorter delays when there was more advertising. In contrast, patients with contraindications had longer delays.<sup>88</sup> It is difficult to square these systematic studies with the more popular perception that these drugs were associated with widespread, inappropriate prescribing.

A recent study examined the relationship between reported adverse drug reactions and pharmaceutical promotion and advertising for drugs to treat arthritis pain, depression, high cholesterol, and allergies.<sup>89</sup> It found that DTC advertising was associated with more adverse drug reactions for arthritis pain medications and depression medications, but not for drugs for high cholesterol or allergies. For arthritis pain drugs, promotion to physicians was also significantly related to adverse drug reactions. Moreover, the effect of promotion to physicians was greater than the effect of DTC advertising. A one standard deviation increase in detailing expenditures increased adverse drug reactions by 60%, but a one standard deviation increase in DTC advertising increased such events by 20%. For cholesterol drugs, promotion to physicians was associated with fewer adverse drug reac-

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<sup>86</sup> Richard L. Kravitz et al., *Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial*, 293 JAMA 1995 (2005).

<sup>87</sup> W. David Bradford et al., *How Direct-to-Consumer Television Advertising for Osteoarthritis Drugs Affects Physicians' Prescribing Behavior*, 25 HEALTH AFF. 1371 (2006).

<sup>88</sup> W. David Bradford et al., *The Effect of Direct to Consumer Television Advertising on the Timing of Treatment*, 48 ECON. INQUIRY 306 (2010).

<sup>89</sup> See Guy David et al., *The Effects of Pharmaceutical Marketing and Promotion on Adverse Drug Events and Regulation*, AM. ECON. J., Nov. 2010, at 1.

tions.<sup>90</sup> Particularly given the differences in results across drug categories, the study provides little basis for general restrictions on DTC advertising.

The more recent argument for restrictions on DTC advertising, growing from the Vioxx recall, is that when drugs are first introduced on the market, there is inevitably a risk of side effects that were not detected in clinical trials.<sup>91</sup> This risk is unavoidable, because relatively low probability side effects may be more than sufficient to justify removing a drug from the market, but cannot reliably be detected in any feasible premarket trials. Instead, they can only be identified after substantial numbers of patients have used the drug. Until we have accumulated this experience base, there is more risk in prescribing a new drug for a particular condition than in using an older drug with a better-understood risk-benefit profile.

Prohibiting or delaying advertising, however, would simply prolong the time it takes to accumulate the necessary experience. Suppose, for example, we cannot detect a particular side effect until one million patients have used the drug for some period of time. Until that experience is accumulated, we will not know the side effect exists. To be sure, patients who are early adopters of the new drug will be at risk. Restricting advertising, however, simply means that it will take longer to accumulate the necessary experience base because manufacturers cannot tell consumers about the product. The first million patients will be at risk in either case, but the risk will be spread out over a longer period of time.

Moreover, consumers who do not know the drug exists may continue to suffer from an untreated condition, particularly if they have tried and rejected the “conventional” therapies for the condition. Because the government’s decision to allow the drug on the market reflects a conclusion that the benefits of the product are sufficiently great to justify its known risks (and presumably the unknown risk of unrecognized side effects as well), it is difficult to see any justification for denying those benefits to willing consumers simply because they lack information about the product’s availability. This is rationing of the availability of the latest medical treatment based not on risk, but on governmentally enforced ignorance. Such a policy is not consistent with the First Amendment.

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<sup>90</sup> *Id.* at 19-20.

<sup>91</sup> *See* Vladeck, *supra* note 76.

## CONCLUSION

The free flow of information is critical to the effective performance of competitive markets. In turn, markets are a vital servant of consumer welfare. Markets reveal what is important and what is not. Regulators decide something is, or should be, important to consumers and impose it, whether by regulating the product itself or by requiring additional information. Markets respond rapidly to changes in preferences and changes in circumstances. Regulations tend to remain in place indefinitely, whether or not they remain worthwhile or even relevant. Markets synthesize and reveal information systematically; regulators frequently make decisions with only limited information available about the true costs and benefits of their actions. Markets are driven by the marginal consumer, who is indifferent between purchasing and doing without the product. Competition for the marginal consumer determines the competitive price and product characteristics, which in turn offer significant consumer surplus to most consumers. Regulatory choices are driven by preferences of the average consumer, pricing some out of the market entirely and leaving others with less consumer surplus than they would otherwise have realized.

To be sure, real markets are imperfect, and intervention can improve their performance. The goal of intervention, however, should be to enhance market performance, not to supplant market outcomes. Interventions can reduce the costs of obtaining information, or ensure the reliability of information that is provided. They can also, however, suppress information that is valuable to consumers and that sellers are willing to provide.

Intervention in markets for information is often particularly tempting. Restrictions on the flow of information generate little in the way of direct compliance costs, and can provide a politically attractive way to address a difficult substantive problem. For example, restricting DTC advertising to address the inherent problem that rare but important side effects can only be detected after a drug has been on the market for some period of time will do little to change the underlying risks. Restrictions on truthful speech, however, provide a questionable “solution” to the problem.

Whether from a First Amendment or an economic perspective, keeping consumers ignorant is rarely an appropriate solution to a market problem. Precisely because information is both valuable and costly, policy should seek to enhance its flow to those who need it. Moreover, an understanding of the impact of even seemingly innocuous interventions such as disclosure requirements should inform the legal analysis of restrictions on speech. Properly applied, the commercial

speech doctrine should prevent undue interference in the market for information.