

**BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

**In the Matter of
Request for Comment on First Amendment Issues**

Docket No. 02N-0209

**Comments of the Staff of
the Bureau of Economics,
the Bureau of Consumer Protection,
and the Office of Policy Planning
of the Federal Trade Commission**

September 13, 2002*

***These comments represent the views of the staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission. They are not necessarily the views of the Federal Trade Commission or any individual Commissioner. The Commission has, however, voted to authorize the staff to submit these comments.**

enforcement when false and misleading advertising occurs. However, available evidence suggests that the general benefits of an enforcement approach that encourages dissemination of truthful information, while vigorously attacking 4

misleading claims about the nutrient content and health benefits of foods, such as in the trans fatty acid example described below.

C The FDA's current approach to direct-to-consumer advertising of prescription drugs has permitted an increase in the flow of truthful information about these products to consumers, and available empirical evidence suggests that this approach may benefit consumer welfare.

The FDA has historically employed its authority to ensure that health care providers and consumers receive accurate and complete information. In doing so, the FDA must balance the right to receive and impart important health information against the need to ensure that consumers are not misled. For the FDA, this balancing must take into account that the "importance of FDA vigilance is heightened given the nature of many of the products FDA regulates, some of which are extremely complex and which have the potential to harm as well as help."⁵ Thus, while the FDA acknowledges in the *Request for Comment on First Amendment Issues* that "there may be tension between some aspects of FDA's authority and judicial developments," it also stresses that it "must continue to pursue regulation of products for purposes of protecting the public with a full recognition of the evolving judicial landscape in areas that directly affect its ability to regulate words."⁶

The Federal Trade Commission and the Food and Drug Administration share a basic mission to protect consumers. Although there are differences in the mandates of the FTC and the FDA, there is also substantial overlap. Both agencies are charged with taking action to stop the dissemination of inaccurate or unsubstantiated information about the safety and efficacy of products and services. We recognize, of course, that the FDA has to evaluate the extent to which this model comports with its core responsibilities in the various areas over which it has authority.⁷ The FTC staff hopes that its

description of the Commission's model and its discussion of empirical evidence about the effects of different regulatory approaches will help inform the FDA in its efforts to implement its own labeling and advertising laws and policies.

II. FUNDAMENTAL COMMERCIAL SPEECH PRINCIPLES

A. Basics of Commercial Speech Doctrine

First Amendment commercial speech jurisprudence is premised on the value to consumers and competition of the free flow of truthful information. In *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council*,⁸ the Supreme Court held that commercial speech, including most advertising and labeling,⁹ was entitled to protection under the First Amendment. In that case, Virginia wto fescussrcipret

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indispensable.

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And if it is indispensable to the proper allocation of resources in a free enterprise system, it is also indispensable to the formation of intelligent opinions as to how the system ought to be regulated or altered. Therefore, even if the First Amendment were thought to be primarily an instrument to enlighten public decision-making in a democracy, we could not say that the free flow of information does not serve that goal.¹²

The Court therefore struck down the ban on price advertising that Virginia had imposed on pharmacists to prevent harm to their professional reputation purportedly caused by such ads.

In *Central Hudson Gas & Electric Corp. v. Public Service Commission*,¹³ the Supreme Court articulated a four-part test for courts to apply in evaluating whether government restrictions on commercial speech are constitutional. First, if the commercial speech concerns unlawful activity or is misleading, it is not protected by the First Amendment. Second, if the commercial speech concerns lawful activity and is not misleading, the court will ask “whether the asserted governmental interest is substantial.”¹⁴ Third, if it is substantial, the court “must determine whether the regulation directly advances the governmental interest asserted.”¹⁵ Fourth, the court must determine “whether [the regulation] is not more extensive than is necessary to serve that interest.”¹⁶ To survive a First Amendment challenge, the government has the burden of proving that its restriction on commercial speech satisfies the *Central Hudson* test.¹⁷

B. Recent FDA Commercial Speech Cases

Neither *Virginia Board of Pharmacy* nor *Central Hudson* considered the issue of restrictions the FDA had imposed on commercial speech. In two recent cases, courts have applied the *Central*

Hudson test to commercial speech restrictions imposed by the FDA. In *Pearson v. Shalala*,¹⁸ manufacturers of dietary supplements sought pre-approval from the FDA for four health claims that the manufacturers wanted to make in labeling for their products. The FDA refused to approve the four health claims on the grounds that they were not supported by the agency’s “significant scientific agreement” standard of evidence. The FDA, consistent with agency practice, refused to consider the manufacturers’ argument that the use of disclaimers could prevent these four health claims from being misleading.

On appeal from a district court decision upholding the constitutionality of the FDA’s determination, the D.C. Circuit reversed. The court focused on the government’s argument that health claims for dietary supplements are “potentially misleading” to consumers if significant scientific agreement does not support the claims.¹⁹ Consumers, according to the government, could be defrauded because they would have “difficulty in independently verifying these claims” and they might “assume that the government has approved such claims.”²⁰ To prevent fraud, the government contended that it could ban dietary supplement health claims that significant scientific agreement does not support.

The D.C. Circuit rejected the government’s argument. It recognized that the government has a substantial interest in ensuring the accuracy of consumer information in the marketplace and banning potentially misleading health claims would appear to directly advance that interest.²¹ The court, however, held that the government did not meet its burden of proving that there was a reasonable fit between banning these claims and the government’s interest in the prevention of fraud.²²

The court explained that the First Amendment commercial speech doctrine embodies a

“preference for disclosure over outright suppression.”²³ Given this preference, it is clear that the government “disregards a far less restrictive means” of advancing its interest “where it chooses a policy of suppression over disclosure - at least where there is no showing disclosure would not suffice to cure misleadingness.”²⁴ The court held that, because the government had not considered whether disclaimers could have eliminated the potential for misleading consumers, its ban on the four health claims violated the First Amendment.

Earlier this year, in *Western States Medical Center*, the Supreme Court applied the *Central Hudson* test to another ban on commercial speech about an FDA-regulated product, compounded drugs. Compounded drugs are created when a pharmacist combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Under the Food and Drug Administration Modernization Act of 1997 (“FDAMA”), compounded drugs were exempt from the FDA’s ordinary drug approval process so long as pharmacists did not advertise, promote, or solicit prescriptions for them.

The lower courts held that FDAMA’s ban on commercial speech for compounded drugs violated the First Amendment, and the Supreme Court affirmed on appeal. Because FDAMA prohibited truthful and non-misleading commercial speech for compounded drugs, the Court applied the last three parts of the *Central Hudson* test to determine whether the government’s restrictions passed constitutional muster. The Court said that the government had a substantial interest in drawing a line between: (1) the compounding of drugs occurring on such a small scale that it is not economically feasible to conduct the safety and efficacy tests needed to obtain regulatory approval from the FDA; and (2) the manufacturing of drugs occurring on a sufficient scale so

that it is economically feasible to do the testing needed for regulatory approval.²⁵ The Court then assumed that, because “without advertising it would not be possible to market a drug on a large enough scale to make safety and efficacy testing economically feasible,”²⁶ prohibiting commercial speech about compounded drugs directly advanced the government’s interest in drawing a line between small-scale compounding and large-scale drug manufacturing.

Even assuming that the commercial speech prohibitions directly advanced this substantial governmental interest, the Court concluded that they were more extensive than necessary. If the government “could have achieved its interests in a manner that does not restrict speech, or that restricts less speech,”²⁷ then a prohibition on commercial speech is more extensive than necessary. The Court concluded that there were a number of alternatives the government could have used to distinguish between small-scale compounding and large-scale drug manufacturing, including prohibiting equipment that can be used to compound drugs on a commercial scale, barring pharmacists from offering compounded drugs at wholesale, or imposing an absolute limit on interstate sales of compounded drugs by a pharmacist.²⁸ Accordingly, it held that the government’s ban on commercial speech about compounded drugs violated the First Amendment because it did not meet the last part of the *Central Hudson* test.

following:

- (1) The free flow of truthful and non-misleading commercial speech empowers consumers to make better-informed purchasing decisions and maximizes consumer welfare.²⁹
- (2) If commercial speech is false or misleading, the government may ban it entirely because it does not assist consumers in making better purchasing decisions.³⁰
- (3) If commercial speech is truthful and non-misleading, the government must prove that any restriction on that speech directly advances a substantial government interest and that the restriction is no more extensive than necessary.³¹

Subsequent cases make clear that:

(A) The government does not have a substantial interest in “preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.”³²

(B) The government does have a substantial interest in restricting the dissemination of commercial speech that has the potential to mislead consumers.³³

(1) The requisite fit between the government restriction and its objective must be “a fit that is not necessarily perfect, but reasonable . . . that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective.”³⁴

(2) When the government seeks to impose a ban on potentially deceptive speech, the courts have said that “at least where there is no showing that disclosure would not suffice to cure misleadingness,” the “government disregards a far less restrictive means” to achieve its objective.³⁵ However, if a potentially misleading claim is “incurable by disclaimer [the government can] ban it outright.”³⁶

These First Amendment principles create a general framework for analyzing the constitutionality of government regulation of commercial speech. Consumer protection agencies, including both the FTC and the FDA, often must choose between the risk of allowing commercial speech that could turn

pre-approve advertising for prescription drugs, it does pre-approve labeling, and drug manufacturers submit prescription drug advertising to the agency for review prior to dissemination.⁴³

An important goal of both the FDA and the FTC is to curb false or deceptive claims, whether in labeling or advertising, and to stop products from being marketed in a way that jeopardizes the safety of consumers. The agencies generally have used different approaches in their efforts to satisfy these objectives, however.

In most instances, the FTC proceeds by identifying and prohibiting deceptive claims, usually in individual cases.⁴⁴ Advertisers, therefore, remain free to make any other claims they want, so long as the claims are truthful, not misleading, and substantiated. This approach provides considerable flexibility because it recognizes the importance of specific wording and the context of the claim, including how the claim is qualified, in determining whether it is illegal.⁴⁵ The FTC imposes targeted remedies to stop deception; it does not require broad pre-market approval of categories of claims,⁴⁶ as does the FDA in the examples noted above. The Commission's targeted approach to preventing deception in the marketplace, and its emphasis on remedies that provide consumers with more information – rather than less – to prevent future deception, dovetail with First Amendment principles intended to promote the free flow of truthful and non-misleading commercial speech.⁴⁷

The FTC's approach is also consistent with vigorous protection of consumers. The Commission has a long and successful history of bringing enforcement actions against deceptive advertising claims, including numerous actions challenging false and unsubstantiated advertising claims about the efficacy and safety of food products,⁴⁸ dietary supplements,⁴⁹ over-the-counter drugs⁵⁰ and

medical devices.⁵¹ The FTC staff, of course, acknowledges that its post-market enforcement model clearly will not stamp out all false or misleading claims. For instance, even aggressive case-by-case law enforcement has yet to stem the tide of deceptive claims for weight loss products.⁵² For the most part, however, the FTC enforcement model discussed below has been both useful in attacking deception in the marketplace and sufficiently tailored to comply with the First Amendment.⁵³

A. Legal Framework

The Commission's authority derives from Section 5 of the

1. Identifying Claims

At the time of dissemination, advertisers must have substantiation not only for what they say expressly in an ad, but also for claims that are suggested or implied by the ad. The Commission therefore looks not just at the literal truth of individual statements in isolation, but at the ad as a whole, assessing the “net impression” conveyed by all elements of the ad, including the text, product name, and depictions.⁵⁹ When an ad lends itself to more than one reasonable interpretation, the advertiser is responsible for substantiating each interpretation. The meaning of the ad and the likelihood of deception is considered from the perspective of a reasonable member of the audience to whom the ad is directed.⁶⁰ What constitutes deception may be different, for example, for advertising aimed at the terminally ill, a group that might be particularly vulnerable to exaggerated cure claims, than it would be for advertising aimed at health professionals whose experience has given them expertise in the advertised products.⁶¹

An ad can be deceptive either by what it says affirmatively or by what it fails to say. The Commission will examine whether an ad omits any important qualifying information necessary to prevent an affirmative representation from being misleading.⁶² Advertising may also be deceptive by simply remaining silent, if doing so communicates an implied, false representation.⁶³ Not all omissions are deceptive, however, even if providing the information would benefit consumers. An omission is deceptive only if the absence of the information causes the advertisement to give the audience an inaccurate impression of the product and its benefits.⁶⁴

To determine what claims are made in an ad, the FTC carefully examines any disclaimers or disclosures to make sure that they are sufficiently clear and prominent to convey the qualifying

information effectively. Qualifications are ineffective unless they are both noticed and understood by consumers. A fine print disclosure at the bottom of a print ad or a brief video superscript in a television ad is unlikely to qualify a claim effectively.⁶⁵ The FTC has provided guidance on what constitutes a clear and prominent disclosure, focusing on specific elements such as clarity of language, relative type size and proximity to the claim being qualified, and an absence of contrary claims, inconsistent statements, or other distracting elements that could undercut the disclosure.⁶⁶

Although the Commission has generally favored disclosures over banning claims as a means of curing deception, disclosures must be crafted with care. The FTC staff has carefully examined the efficacy of disclosures in food and supplement advertising to qualify various types of nutrient and health claims.⁶⁷ Its 1998 report on a generic copy test of various food and dietary supplement advertising claims (“Food Copy Test”) reveals the challenges associated with crafting disclosures that accurately convey the intended message to consumers. The test results suggest that consumers may misconstrue some qualifying disclosures as part of the seller’s promotional message, thereby reinforcing rather than limiting the claim. Explicit disclosures about the negative implications of the information were less likely to be susceptible to misinterpretation as a positive sales message.⁶⁸

The importance of explicit disclosures is also evident in the case of health claims discussing areas of emerging science. Vague qualifiers that a food or nutrient “may” have a certain health benefit had little or no impact on consumers’ perception of the certainty of the science. By contrast, disclosures that stress the need for further research and alert consumers to ongoing scientific debate are most effective in conveying that the science is not yet established.⁶⁹ The Food Copy Test appears to confirm that claims involving complicated scientific concepts require careful and detailed qualification.⁷⁰

Because of the challenges inherent in accurately presenting claims about emerging areas of science, the Commission has provided specific guidance on how to qualify these claims.⁷¹ As discussed above, the First Amendment case law considers, *inter alia*, whether a less restrictive alternative, such as a mandated disclosure, would be adequate to qualify such a claim, and the FD, and the FD, and thp, t ld thn, t f the challen

In applying these factors to health related claims for products like foods, OTC drugs, supplements, and devices, the Commission typically requires “competent and reliable scientific evidence” to substantiate efficacy or safety claims. The term has been defined in numerous FTC cases as “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”⁷⁷ The competent and reliable scientific evidence standard is intended to be rigorous but not inflexible. It provides some leeway to ensure that consumers have access to truthful, well-qualified information about emerging areas of science, while at the same time ensuring that consumers can have confidence in the accuracy of claims.⁷⁸

3. Analyzing the Materiality of a False or Misleading Claim

The final step the Commission must take in finding that a false or misleading claim or omission is deceptive is to determine if it is “material.” A material misrepresentation is one likely to affect a consumer’s choice of or conduct regarding a product, *i.e.*, information that is important to consumers.⁷⁹ Many claims are presumptively material, such as express claims, health claims, and safety claims.⁸⁰ Other claims are not presumed material, and so the Commission may analyze evidence to determine whether these claims were important to consumers. This evidence may include information showing: (1) that the general subject matter of the claim was important to consumers,⁸¹ (2) that the advertised product sold at a price premium compared to its competitors,⁸² (3) the advertiser’s own assessment of the success of its claims,⁸³ or (4) a correlation between the dissemination of the claims and increased sales of the advertised product.⁸⁴

C. Constitutionality of FTC's Approach

Any FTC enforcement action against deceptive advertising involves developing a record both on the claims conveyed by the ad and on the adequacy of the substantiation for those claims. The record serves to establish the law violation and to guide the agency on the appropriate scope of remedies. (Appendix One provides a practical discussion of how the FTC staff builds its administrative record in deceptive advertising cases). An important objective of the FTC's approach is to foster the free flow of truthful and non-misleading information to consumers. The Commission therefore strives to tailor its remedies to stop deception without imposing unduly burdensome restrictions that might chill information useful to consumers in making purchasing decisions. In doing so, the Commission is applying the same principles that underlie the commercial speech doctrine.

The FTC employs a broad range of remedies to stop deceptive speech. The most basic remedy in any FTC enforcement action is the requirement that the advertiser cease and desist from making the claims found to be deceptive. False or misleading commercial speech does not assist consumers in making decisions in the marketplace, and, consequently, "there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public."⁸⁵ The Supreme Court has consistently held that government may ban false or misleading advertising claims. Such claims are entitled to no First Amendment protection.⁸⁶

In addition to ordering an advertiser to stop the specific practice found to be deceptive, the FTC will usually impose "fencing-in" relief designed to prohibit an advertiser from making similar deceptive claims for the same or similar products. In doing so, the Commission will tailor the relief to ensure that its scope bears a reasonable relationship to the challenged conduct and still ensures that the

remedy on the rare occasions when it finds that the false belief is likely to linger even after the deceptive advertising stops. Like disclosure remedies, corrective advertising remedies have withstood First Amendment challenge, when used to correct lingering misimpressions created by deceptive advertising.⁹⁵

Finally, there have been instances in which the Commission has imposed, by order or rule, requirements that information be disseminated for purposes other than to prevent deception. For instance, pursuant to its authority to prevent unfair acts or practices, the FTC may require the disclosure of significant hidden safety risks associated with a product⁹⁶ or it may require that information be presented in a standardized format that allows consumers to better compare products or services.⁹⁷ The information remedies imposed by the Commission under its unfairness jurisdiction are narrowly tailored to ensure that they are “reasonably necessary” to prevent substantial physical or economic injury, and, therefore, are unlikely to violate the First Amendment.⁹⁸

The FTC staff believes that our experience using sub

value of the commercial speech doctrine to consumers. The evidence shows that different regulatory approaches can have a significant impact on the flow of information, with concrete consequences for consumer choices and health. The evidence discussed in this section confirms the FTC's own experience with advertising enforcement. A flexible approach to commercial speech – one that encourages the dissemination of accurate speech and tailors restrictions to prevent speech that is false or misleading – will result in greater dissemination of valuable information with benefits for both consumers and competition. In contrast, the evidence indicates that broad restrictions on the dissemination of truthful commercial speech, while effectively stopping false or misleading information, can deprive consumers of useful information as well.

The benefits of a flexible approach are especially significant when the information relates to consumer health. Advertising and labeling can be extremely effective tools to educate consumers about diet-disease relationships, to increase their awareness of diseases, to inform them of different treatment options, and to empower them to manage better their own health. The ability to present information in

believes that this empirical evidence will assist the FDA in the current review of its policies, by

health information in food advertising and on food labels. The first relates to a relaxation of food labeling policies in the 1980s to allow more claims to be made about high-fiber diets and cancer risk, with resulting improvements in consumer dietary habits. The second compares the extent of health information, particularly as it relates to fat and saturated fat, in advertising before and after implementation of the Nutrition Labeling and Education Act.

The final example presents the potential benefits that could be realized by implementing the FDA's proposed rule to provide trans fatty acid content information in food labeling.

1. Fiber/Cancer Claims in the Cereal Market

A study on the effects of the dissemination of health information in the ready-to-eat cereal market provides a concrete example of the consumer and competitive benefits of policies that allow such claims for food products.¹⁰⁵ Prior to 1984, health claims were not allowed on the labeling of food products. In 1984, however, the Kellogg Company began claiming on labels and in advertising that All Bran cereal was high in fiber and that diets high in fiber could reduce the risk of cancer, claims that were consistent with the existing recommendations of the National Cancer Institute. Competing cereal manufacturers soon responded with similar claims for their own high-fiber cereals.

The appearance of these fiber/cancer claims was followed by significant changes in consumer cereal choices. By 1987, consumers had substantially increased their consumption of high-fiber cereals, with the greatest increase occurring in the groups that had previously consumed the least amount of high fiber cereal. The profile of the cereal market also changed. The market share for high-fiber cereals increased by almost four percentage points, a \$280 million increase in sales,¹⁰⁶ and more high-fiber cereal products were introduced into the market.¹⁰⁷ In sum, the dissemination of fiber/cancer

claims benefitted consumers by providing important dietary guidance and by expanding the range of high fiber cereal choices available to them in the market.

2. Health Claims for Foods and NLEA

The results of a review of health claims during the 1980s and after the FDA issued its labeling regulations in 1994 to implement the NLEA are consistent with the All Bran example. From 1984 to 1990, advertising and labeling claims increasingly began to link the amount of fat in foods with heart disease and certain cancer risks. Although consumers had begun to cut their fat consumption before these claims appeared, empirical evidence shows that fat consumption fell more dramatically after food marketers begin making these health claims.¹⁰⁸ Consumers also began to reduce their fat consumption across a much broader range of food categories, suggesting that the claims contributed to making consumers aware of the availability of lower fat substitutes for the foods they had been consuming. Advertising and labeling claims linking fat content to heart disease and cancer risk thus appear to have assisted consumers in making healthier dietary choices.

In contrast, the empirical evidence shows that NLEA labeling regulations permitting health claims in labeling only for foods with the “best” overall nutritional profile appear to be associated with a significant decline in health claims in food advertising. A forthcoming FTC Staff Report¹⁰⁹ shows that there has been a slight increase in the percentage of advertising that makes health claims in the fruit, vegetable, and juice product categories. This is consistent with the FDA’s goal of encouraging health claims for foods that are the “best” dietary choices for consumers.¹¹⁰

At the same time, however, there now appear to be very few health claims in advertising for many other types of foods.¹¹¹ One dramatic example is the change in the rate of health claims relating

saturated fat to heart disease. In the 1990 sample, approximately one-third of ads for products like cooking oil and margarine included information explaining the heart health benefits of reducing saturated fat intake. After NLEA regulations restricting health claims to specific qualifying foods were implemented, we found no examples of such health claims in advertising for these same foods.¹¹² With the restriction on saturated fat health claims, however, food marketers also decreased their discussion of the saturated fat content of cooking oils and margarine in the post-NLEA sampled advertising. Additional evidence suggests that, over the same period, consumers may have shifted toward purchasing cooking oils with higher saturated fat content.¹¹³ Thus, it appears that some of the benefits of information about the relative nutritional and health benefits of different food products may have decreased as a result of regulatory policies intended to limit health claims to the “best” dietary choices, and the FDA may want to consider this point when it considers whether less restrictive alternatives are appropriate for its purposes.¹¹⁴

3. Trans Fatty Acid Claims

FDA’s current consideration of labeling claims for trans fatty acid content illustrates yet another example of the consumer benefits that can be realized by adopting policies that encourage more dissemination of truthful and non-misleading information. Existing regulations prohibit food manufacturers from including information about the trans fatty acid content of a food or about the health risks of trans fatty acids on product labels. In a proposal to modify these rules to provide for disclosure of trans fatty acid content and permit “Trans Fat Free” claims in labeling, the FDA noted that few consumers are aware of the substantial evidence linking trans fatty acids to an increase in serum cholesterol and heart disease.¹¹⁵ The FTC staff agrees allowing labeling claims regarding the presence

and effects of trans fatty acids will help raise awareness and permit consumers to choose healthier

advertisements, the FTC staff filed a supporting comment explaining that the proposal would “provide timely information regarding medical advances, remind consumers about good health practices, and supply information needed by consumers to understand and evaluate their physician’s recommendations.”¹¹⁸ The comment also noted two unique gatekeeper features of the prescription drug market, which tend to reduce the likelihood of harm from DTC advertising: (1) the need for a doctor’s prescription and (2) the requirement that drugs be dispensed by pharmacists. Although not definitive, the available empirical evidence suggests that FDA’s current approach is fulfilling its promise and promoting consumer satisfaction.

Several surveys of consumers have been conducted to assess the effects of DTC advertising on consumer attitudes, experiences, and behavior. Major surveys includes those by the FDA,¹¹⁹ Prevention (2001/2002),¹²⁰ and the Henry J. Kaiser Family Foundation (2001).¹²¹ Details of these surveys are discussed extensively in Calfee (2002).¹²²

Consumer surveys suggest that DTC advertising has stimulated discussions between doctors and patients, encouraged consumers to learn more about previously undiagnosed conditions, and not prevented doctors from recommending non-drug therapies. For example, a Prevention magazine survey states:

The apparent effectiveness of DTC advertising is impressive, especially in terms of its ability to stimulate discussions between patients and their doctors. Results from this year’s survey show that 32 percent of all consumers who have seen DTC advertisements have discussed an advertised medicine with their doctor as a direct result of these advertisements. This figure is essentially the same as that seen in research from The Henry J. Kaiser Family Foundation, which showed that 30 percent of consumers who had seen an advertisement spoke with their doctor about an advertised medicine. Both these figures suggest a high level of effectiveness for DTC advertising. In real terms, these numbers mean that DTC advertising motivated an estimated 61.1 million consumers to talk with their doctors about a health condition and

possible treatments for it. For 60 percent of these consumers, these conversations included recommendations for non-drug therapies. Results also show that an estimated 24.8 million consumers were prompted by advertisements for prescription medicines to talk with their doctor about a health condition they had not previously discussed.¹²³

According to the survey, DTC ads have also had benefits with respect to consumer compliance with their drug regimen. “Seventeen percent of consumers who have seen advertisements for a medicine they are taking say that seeing these advertisements makes them more likely to take their medicine regularly. Only 2 percent say the advertisements make them less likely.”¹²⁴

percent said it harmed their relationship.¹²⁶ Consumers thus seem to be generally positive about the effects of DTC advertising on their relationship with their doctor.

Many physician groups have expressed their support for DTC advertising, emphasizing that balanced DTC advertising provides important information to consumers. For example, the National Medical Association, representing African-American physicians, surveyed its members, and issued a statement supporting the role of DTC ads in educating patients about disease and treatment options.¹²⁷ The American Medical Association has also issued positive statements about DTC advertising. In addition, a representative of the National Alliance for Hispanic Health has testified in favor of DTC advertising, noting its ability to reach unique sub-populations. On the other hand, some physicians are concerned that DTC advertising may interfere with their relationship with their patients. For example, the American College of Physicians-American Society of Internal Medicine has expressed its concern that DTC ads confuse and misinform consumers about medications.¹²⁸ The FDA's current surveys to gauge the effects of DTC advertising on consumer and physician attitudes and behavior should shed additional light on this issue.¹²⁹ In addition, further studies addressing the effects of DTC advertising on doctors' prescribing decisions or whether it impedes doctors' ability to provide optimal healthcare would be helpful in understanding the impact of DTC advertising.

Extensive studies investigating the effect of DTC advertising on prices do not exist. In particular, the demand effects have not been extensively studied. The available evidence, however, suggests that any price effects from the costs of advertising itself are likely to be small. DTC advertising expenditures represent only a small component of overall drug promotion spending and are also small in comparison to overall drug sales. Although research shows that spending on DTC advertising has been

rising dramatically, it is only 2.2% of total sales,¹³⁰ and remains small relative to expenditures on professional marketing (such as detailing and free sampling).¹³¹ For example, Rosenthal *et al.* reported that:

Total spending on direct-to-consumer advertising for prescription drugs has been increasing since the early 1990s and has more than doubled since 1996. Despite this rapid growth, such advertising still accounts for only 15 percent of the promotion-related budgets of pharmaceutical companies. The continued importance of promotion to health care

The Federal Trade Commission's experience demonstrates that the First Amendment commercial speech doctrine is fully consistent with its own rigorous consumer protection. In fact, the analysis that the courts have applied to assess the constitutionality of restrictions on commercial speech stands as a model for an approach to consumer protection that the Commission has used successfully in its efforts to prevent or halt the deceptive marketing of foods, drugs, dietary supplements, and other health-related products and services.

The commercial speech doctrine recognizes the importance of consumer access to truthful and accurate information. On the other hand, inaccurate or misleading claims have no protection under the First Amendment and need to be purged from the marketplace to protect and enhance the value of the free flow of truthful information. In practice, consumer protection agencies often must choose between the risk of allowing commercial speech that might prove to be false or misleading and the risk of banning commercial speech that might prove to be true.

Like the balancing that is central to the commercial speech doctrine, the Commission's law enforcement actions under its own mandate strike a balance that is rigorous enough to attack deception, yet flexible enough to encourage accurate claims. A key aspect of that flexible approach is the emphasis on remedies that favor disclosures and qualification of claims over outright bans. The FTC staff believes that its experience in policing advertising and labeling claims may assist FDA in its effort to conform its own regulatory practices to the First Amendment, while still advancing its important mission to protect and promote public health.

6. *Id.*

7. For example, the FTC staff recognizes that the role the FDA performs in the prescription drug approval process is quite different from the role the FTC performs in seeking to curb deceptive advertising.

8. 425 U.S. 748, 771 (1976).

9. Commercial speech includes most advertising and labeling. *See, e.g., Virginia Bd. of Pharmacy*, 425 U.S. 748 (1976) (advertising); *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980) (advertising); *In re R.M.J.*, 455 U.S. 191 (1982) (advertising); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (labels); *Lorillard Tobacco Co. v. Reilly*, 121 S. Ct. 2404 (2001) (advertising and labels).

10. Economic theory and evidence likewise recognize the value of commercial speech to consumers. “Information about price, quality, and other attributes allows buyers to make the best use of their budget by finding the product whose mix of price and quality they most prefer.”

H. Beales, *et al.*, *The Efficient Regulation of Consumer Information*, 24 J.L. & Econ. 491, 492 (1981). Advertising can also reduce the costs consumers must bear when they seek to obtain and evaluate information from a variety of sources. For example, “Sellers can accumulate and substantiate descriptive data about each product line once and make it available to all consumers; each consumer, if society left the task to consumers, would have to do it separately for every purchase of each individual item.” R. Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 Harv. L. Rev. 661, 670 (1977). In short, economics, like commercial speech jurisprudence, acknowledges that advertising is “an immensely powerful instrument for the elimination of ignorance.” G. Stigler, *The Economics of Information*, 64 J. Pol. Econ. 213, 220 (1961).

11. Economic theory and evidence also recognize that commercial speech benefits competition. Advertising helps buyers “locate preferred products [which] gives sellers an incentive to compete to improve their offerings by allowing buyers to find and reward (with patronage) the seller whose offer they prefer. Without such information, the incentive to compete on price and quality will be weakened, and consumer welfare will be reduced.” Beales, *et al.*, *supra* note 6 at 492; *see* Pitofsky, *supra* note 6 at 664 (no “quarrel” with the “premise that information with respect to most product characteristics is available as a result of sellers responding to incentives generated in marketplace”).

12. *Virginia Bd. of Pharmacy*, 425 U.S. at 765.

13. 447 U.S. 557 (1980).

14. *Id.* at 566.

15. *Id.*

16. *Id.*

35. *Pearson*, 164 F.3d at 658. *See, e.g., Western States Med. Ctr.*, slip op. at 11, 18 (holding that a ban on commercial speech for compounded drugs was more extensive than necessary because the government’s interest in preventing consumers from being misled as to drug risks “could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown”) (the government’s interest in preventing misleading advertisements “could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown.”); *Pearson*, 164 F.3d at 660-61 (“[W]hile we are skeptical that the government could demonstrate with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness, we do not rule out that possibility.”); *Washington Legal Found.*, 13 F.Supp.2d at 73 (“The most obvious alternative [to a ban on commercial speech] is full, complete, and unambiguous disclosure by the manufacturer”).

36. *Pearson*, 164 F.3d at 659.

37. Economists refer to the risk of allowing harmful claims as a “Type I error” and the risk of prohibiting beneficial claims as a “Type II error.” J. Calfee & J. Pappalardo, *How Should Health Claims for Foods Be Regulated? An Economic Perspective*, *Economics Issues Paper*, Bureau of Economics of the Federal Trade Commission (1989), at 35.

38. Working Agreement between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,851 (1971). Although the liaison agreement does not refer explicitly to dietary supplements, the two agencies follow the same division of roles for dietary supplements as for food products. Under the Food Drug and Cosmetic Act, dietary supplements are deemed to be foods. 21 U.S.C. § 201(ff).

39. In 1962, Congress amended the Food Drug and Cosmetic Act to eliminate the FTC’s authority under Section 12 of the FTC Act over prescription drug advertising related to the drug name, formula and summary of effectiveness, and consequences of use. *See* 21 U.S.C. § 502(n). The amendment does not limit the FTC’s jurisdiction over statements that fall outside these three categories and does not affect the FTC’s basic advertising authority under Section 5 of the FTC Act. (*See* Letter from the Federal Trade Commission to the Honorable John C. Dingell, August 15, 1983, for further discussion of the FTC’s shared jurisdiction with FDA regarding prescription drug advertising). One recent example of an FTC case involving prescription drug advertising was a challenge to false medical claims about Viagra and Propecia made by online pharmacies. *See Worldwidemedicine.com*, CV-S-00-0861-JBR (D. Nev. July 6, 2000) (Stipulated Final Order).

40. 21 U.S.C. § 354; *see also* 21 C.F.R. Part 314.

41. Before making a health claim in food labeling – that is, a claim that characterizes the relationship between a nutrient and a disease – a manufacturer must first petition the FDA to issue a regulation authorizing the claim. 21 U.S.C. § 343 (r).

Inc., D. 9294 (Sept. 6, 2001) (consent) (challenging claims for Pedi-Active A.D.D. as treatment of Attention Deficit Disorder); *Liverite Prods., Inc.*, SA 01-778 AHS(ANx) (C. D. Cal. Aug. 20, 2001) (Stipulated Final Order) (challenging claims for Liverite supplement to treat/prevent cirrhosis, hepatitis, other liver diseases); *Christopher Enters., Inc.* CV-0505 ST (C. D. Utah Nov. 29, 2001) (Stipulated Final Order) (challenging claims for comfrey products as safe and effective for various conditions and prohibiting future marketing of comfrey for ingestion); *Lane Labs-USA*, CV-003174(WGB) (D. N.J. July 6, 2000) (Stipulated Final Order) (challenging claims for shark cartilage as treatment for cancer); *Enforma Natural Prods., Inc.*, 04376JSL(CWx) (C.D.Cal. April 25, 2000) (Stipulated Final Order) (challenging weight loss claims for Fat Trapper and Exercise in A Bottle supplements).

50. *See, e.g., Novartis Corp.*, D. 9279 (Decision and Order) (Aug. 18, 2000), *aff'd* 223 F. 3d 783 (D.C. Cir. 2000) (challenging comparative back pain relief claims for Doan's Pills); *Bayer Corp.*, CV-00-132 (NHP) (D.N.J. Jan. 11, 2000) (Consent Decree) (challenging claims for heart attacks/stroke benefits of aspirin in general population); *Pfizer, Inc.*, C-3841 (Dec. 14, 1998) (consent) (challenging efficacy claims for head lice treatment); *Johnson & Johnson Consumer Prods., Inc.*, C-3636 (Jan. 18, 1996) (consent) (challenging claims for protection against HIV and other diseases for K-Y Plus spermicidal lubricant).

51. *See, e.g., Ab Energizer, LLC*, 02CV888H(AJB) (S.D. Cal. May 8, 2002) (complaint filed) (challenging claims for Ab Energizer exercise device); *Michael Forrest, dba Jaguar Enters.*, C-4020 (July 30, 2001) (consent) (challenging cancer, AIDS and other disease claims for various electronic therapy devices); *Pain Stops Here!, Inc.*, C-3898 (Sept. 7, 1999) (consent) (challenging pain claims for magnetic therapy device).

52. Weight loss advertising is one area where the Commission sees many examples of fraudulent claims. The Commission is preparing to release a staff report on weight loss advertising that reveals widespread deception in this industry despite aggressive enforcement efforts by the agency, including bringing more than 150 cases.

53. While pursuing fraud and deception cases are the mainstays of the FTC's consumer protection mission, consumer education is also a vital line of defense for consumers. With each major consumer protection uoging clStiomparnging pain easd1 lahses g comrehfensive andctreasive educationcxamaigan.r

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or is likely to cause, substantial injury to consumers, which is not reasonably avoidable by consumers themselves and is not outweighed by countervailing benefits to consumers or competition. 15 U.S.C. § 45 (n). *See also* Unfairness Policy Statement, appended to *International Harvester Co.*, 104 F.T.C. 949, 1070 (1984). The Commission's unfairness authority focuses on balancing the costs and benefits of particular practices and provides an alternative to a deception analysis. The Commission has relied on its unfairness authority, for example, to address the failure of an advertiser to disclose a serious safety hazard associated with a product. *See* discussion on the omission of safety information in Section B.1. *infra*.

57. The Commission has developed an extensive body of case law and has issued two policy statements, the Deception Policy Statement and the Statement on Advertising Substantiation, that articulate the basic elements of this analysis. Deception Policy Statement, appended to *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 174 (1984); and Substantiation Policy Statement, appended to *Thompson Med. Co.*, 104 F.T.C. 648, 839 (1984).

58. This has been defined in FTC cases as "tests, analyses, research, studies, or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by others in the profession or science to yield accurate and reliable results." *See, e.g., Schering Corp.*, 118 F.T.C. 1030, 1127 (1994).

59. *See, e.g., Thompson Med. Co.* 104 F.T.C. 648, 842-43 (1984) (implied claim that Aspercreme contained aspirin conveyed by net impression of ad, including product name), *aff'd* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

60. Deception Statement at 177.

61. *Id.* at 179.

62. Deception Statement at 175, n.4; *see also International Harvester Co.*, 104 F.T.C. 949, 1057 (1984). In addition to constituting a violation of Section 5's general prohibition against deceptive practices, an omission may also violate Section 12's prohibition against false advertisements for foods, drugs, devices and cosmetics. Section 15 defines "false advertisement" for purposes of Section 12, as

63. Deception Statement at 177. Thus, if a product poses significant safety risks, the failure to disclose them may be deceptive even in the absence of any safety claim. See discussion in Supplement Guide at Section A.2. The Commission has also challenged the pure failure to disclose information, especially where it relates to a serious risk of physical injury, under its unfairness authority. See also *Consumer Direct, Inc.*, 113 F.T.C. 923 (1990) (consent) (failure to disclose that stomach exercise device frequently broke and caused serious injury challenged as unfair).

64. Deception Statement at 177.

65. See, e.g., *Haagen-Dazs Co.* 119 F.T.C. 762 (1995)(consent order); *Stouffer Food Corp.*, 118 F.T.C. 746 (1994); *Kraft, Inc.*, 114 F.T.C. 40, 124 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert denied*, 507 U.S. 909 (1993) .

66. Deception Statement at 180; Supplement Guide at Section A.3; *Thompson Med. Co.* 104 F.T.C. at 842-43; see *Figgie Int'l, Inc.*, 107 F.T.C. 313, 401 (1986), *aff'd*, 817 F.2d 102 (4th Cir. 1987); see also *FTC v. Brown & Williamson Tobacco Corp.*, 778 F. 2d 35 (D.C. Cir. 1985); *Katherine Gibbs, Inc. v. F.T.C.*, 612 F. 2d 658, 666 (2d Cir. 1979). The Commission also recently published a business education piece on the use of disclosures in Internet advertising. *Dot Com Disclosures: Information about Online Advertising*, < <http://www.ftc.gov/bcp/online/pubs/buspubs/dotcom> >.

67. D. Murphy, *et al.*, Generic Copy Test of Food Health Claims in Advertising, Joint Staff Report of the Bureaus of Economics and Consumer Protection, Federal Trade Commission (1998) (Food Copy Test).

71. Both the Commission's Food Policy Statement and Supplement Guide stress the importance of crafting disclosures that clearly convey the limits on the scientific evidence supporting a claim as well as the existence of any significant contrary evidence. Both also indicate that even a carefully qualified claim is likely to be deceptive in violation of the FTC Act when it runs contrary to a larger body of evidence. Food Policy Statement at Section IV.A.; Supplement Guide at Section A.3.

72. A claim that a food product has a specific nutrient content when it does not is one example of a false claim. *See, e.g., Clorox Co., C-3427* (May 17, 1993) (consent) (challenging claims that Take Heart salad dressings were fat free as false). The FTC has also challenged, as false, claims that test kits can detect the presence of a disease or pathogen when laboratory testing of the kits found them to be ineffective. *See, e.g., Vital Living Prods., Inc., 3:02CV74-MU* (W.D.N.C. Mar. 13, 2002) (Stipulated Final Order) (claims for PurTest anthrax detection kit challenged as false).

73. The substantiation doctrine is based on deception. An objective claim also implies to consumers that there is evidence supporting the claim. When this implied claim of support is false or misleading, the ad is deceptive. *See* Substantiation Statement at 839-40.

74. *See, e.g., FTC v. SlimAmerica, Inc., 77 F. Supp. 2d 1263* (S.D. Fla. 1999). SlimAmerica's advertising for its weight lost supplement included various claims like "Dramatic Proof From Leading

while still allowing the agency to adapt its standard to reflect what experts in the relevant discipline would generally consider to be an adequate level of support. These principles are set out in detail in the Supplement Guide, as well as in various FTC cases. *See* Supplement Guide at Sections B.1-5; *see also Schering Corp.* In assessing the science, the Commission examines both the validity of individual studies and the surrounding context of the scientific literature to determine whether the weight of the evidence supports the claim. A single, well conducted study may be adequate to support a limited claim, if there are no other studies reaching contrary conclusions. The Commission also evaluates whether the evidence relates to the specific product and to the specific characterization of the benefit being advertised. For example, the Commission will consider whether the advertised product use the same dose, formula, and form of administration as the product that was used in the studies cited as substantiation. For that reason, the presentation of the claim and how it is qualified is integral to an assessment of the substantiation. An unqualified claim suggesting that science has “proven” a specific health benefit, for example, might be deceptive if the science is still emerging, whereas a more qualified claim about the same health benefit might be permissible.

79. Deception Statement, 103 F.T.C. at 182; *Novartis Corp.*, slip op. at 11-12; *Kraft, Inc.*, 114 F.T.C. at 134.

80. *See id.*

81. *See Novartis Corp.*, slip op. at 15; *Kraft, Inc.* 114 F.T.C. at 135; *Thompson Med. Co.*, 104 F.T.C. at 817.

82. *See Novartis Corp.*, slip op. at 15; *American Home Prods. Corp.*, 98 F.T.C. 136, 369 (1981), *aff'd*, 695 F. 2d 681 (3d Cir. 1982).

83. *See Kraft, Inc.*, 114 F.T.C. at 136.

84. *See id.* at 138.

85. *Central Hudson*, 447 U.S. at 557.

86. *Virginia Bd. of Pharmacy*, 425 U.S. at 771; (“Untruthful speech, commercial or otherwise, has never been protected for its own sake.”); *In re R.M.J.*, 455 U.S. at 203 (“Misleading advertising may be prohibited entirely.”); *Porter & Dietsch, Inc. v. FTC*, 605 F. 2d 294, 304 (D.C. Cir. 1979) (“Advertising receives no protection from the First Amendment” if it is “false and misleading.”); *FTC v. Pharmatech Research, Inc.*, 576 F. Supp. 294, 303 (D.D.C. 1983) (“The First Amendment does not

88. See, e.g., *Bristol-Myers Co. v. FTC*, 738 F. 2d 554, 562 (2d Cir. 1984); *Sears Roebuck & Co. v. FTC*, 676 F. 2d 385, 400 (9th Cir. 1982); *Litton Indus. v. FTC*, 676 F. 2d 364, 373 (9th Cir. 1982); *United States v. Reader's Digest Ass'n*, 662 F. 2d 955, 965 (3d Cir. 1981); *Jay Norris, Inc. v. FTC*, 598 F. 2d 1244, 1252 (2d Cir. 1979).

89. Note that the court in *Pearson* recognized that there might be situations where the deceptive nature of a claim would be incurable by disclaimer, giving the specific example of a health claim not supported by the weight of the scientific evidence. In such a situation, the Court indicated that an outright ban on the claim would be constitutionally permissible. 164 F. 3d at 659. The Supreme Court has been quite skeptical, however, of broad restrictions on potentially misleading claims, noting that:

94. *Zauderer*, 471 U.S. at 651; *see also Ibanez v. Florida Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 146 (1994). For example, a requirement that a company disclose more information than is necessary to prevent deception may not pass constitutional muster. *See FTC v. National Comm'n on Egg Nutrition*, 570 F. 2d 157, 164 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978).

95. *See, e.g., Novartis Corp. v. FTC*, 223 F. 3d 783, 789 (D.C. Cir. 2000); *see also Warner-Lambert Co. v. FTC*, 562 F. 2d 749 (D.C. Cir. 1977) (FTC corrective advertising remedy upheld against First Amendment challenge).

96. *See, e.g., International Harvester Co.*, 104 F.T.C. at 1064-70. The Commission found respondent's failure to disclose a serious fuel geysering hazard associated with its gasoline tractor to be an unfair practice in violation of the FTC Act and indicated that a disclosure requirement would be an appropriate remedy. Because respondent had already engaged in voluntary notification of customers and no longer manufactured the tractors, however, no order was imposed.

97. The Commission's R-Value Rule, for example, requires that manufacturers present comparable heat flow resistance ratings and other information in a standardized format on labels and in ads to assist consumers in making home insulation purchasing decisions. 16 C.F.R. Part 460.

98. There is relatively little case law to provide guidance as to the extent to which disclosure requirements required for purposes other than to prevent deception will be held to comply with the First Amendment. *Compare National Elec. Mfrs. Ass'n v. Sorrell*, 272 F. 3d 104, 115 (2nd Cir. 2001), *cert. denied*, 122 S. Ct. 2358 (2002) (statute requiring that labels disclose presence of mercury and the importance of recycling products with mercury to "better inform consumers about the products they purchase" did not violate the First Amendment), *with International Dairy Foods Ass'n v. Amestoy*, 92 F. 3d 67 (2nd Cir. 1996) (statute requiring that, to satisfy "consumer curiosity," retailers must label milk from cows who had been given certain bovine hormones violated the First Amendment).

99. The FTC also enforces some special statutes that restrict commercial speech or otherwise require the disclosure of information for purposes other than to prevent deception or unfairness. The Commission recently successfully defended one of these special statutes, designed to protect consumer privacy, against a First Amendment challenge. *Trans Union Corp. v. FTC*, 245 F. 3d 809 (D.C. Cir. 2001), *cert. denied*, 122 S. Ct. 2386 (2002).

100. Research shows that consumers generally construe claims appearing on the front or side panels of food packages as promotional messages similar to advertising, but they do not construe the nutrition

and Drug Administration, Washington, DC (Jan. 1996); A. Levy, PHS Food Label Health Claims Focus Group Report, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Market Studies (1995).

101. As mandated by the NLEA, FDA's nutrient content labeling regulations require a number of disclosures. These mandated disclosures include, but are not limited to: (1) a referral statement to the nutrition panel, required whenever a nutrient content claim is made, 21 C.F.R. § 101.13(g), (2) disclosure of nutrients (fat, saturated fat, cholesterol, and sodium) present in a food at a level that FDA has concluded increases the risk of diet-related disease, required whenever a nutrient content claim is made, 21 C.F.R. § 101.13(h), and (3) "triggered" disclosures of the amount of certain related nutrients when claims concerning fiber, saturated fat, and cholesterol appear. 21 C.F.R. § 101.54(d) (requirements for fiber claims); 21 C.F.R. § 101.62(c) (requirements for saturated fat claims); 21 C.F.R. § 101.62(d) (requirements for cholesterol claims).

102. Advertising and labeling also generally complement one another. Consumers who see a nutrient content claim or a health claim in an ad for a food product may be reminded of the claim if they see similar information on the product's label in the grocery store. Consumers who see such claims in labeling at the grocery store likewise may remember similar information they saw in an ad for the food product.

103. Commercial speech may also reach some consumers who are exposed to advertising and labels, but who do not normally pay attention to the health and nutrition issues discussed in government educational pamphlets or the popular press. For example, according to a recent survey of 4,200 food shoppers, 70% of brand purchase decisions are made in the store, the point at which consumers are being directly exposed to label information. Point of Purchasing Advertising Institute, 1996 POPAI Consumer Buying Habits Study, 8 (1996).

104. Commercial speech cases recognize that this incentive is one important part of the role commercial speech plays in facilitating efficient markets. *See, e.g., Va. Bd. of Pharmacy*, 425 U.S. at 765 (“[Commercial speech] is indispensable to the proper allocation of resources in a free enterprise system.”).

105. P. Ippolito & A. Mathios, Health Claims in Advertising and Labeling: A Study of the Cereal Market, FTC Staff Report (1989).

106. *Id.* at 33.

107. Cereals introduced between 1985 and 1987 averaged about 2.6 grams of fiber per ounce of cereal, compared to an average of only 1.7 grams for cereals introduced between 1979 and 1984. In addition, not only did fiber content increase, but sodium and total fat content in the high fiber brands decreased. *Id.*

108. P. Ippolito & A. Mathios, Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990, FTC Staff Report (1996). For women, average fat consumption fell by 3.7 grams per day between 1977 and 1985, and then fell by an additional 7.5 grams per day from 1985-1990. For men, the decline in daily fat consumption during the first period is 5.3 grams, and almost 15 grams during the next five years.

109. P. Ippolito & J. Pappalardo, Advertising Nutrition & Health: Evidence from Food Advertising, FTC Staff Report (2002). The forthcoming staff report analyzes the content of all food advertisements appearing in a sample of five leading women's magazines and three general readership magazines over the period 1977 to 1997, a period that spans several changes in government regulation of food labeling and advertising.

110. Consumers, however, may not have received more health information overall about fruits, vegetables, and juices. Although the percentage of ads reviewed showed an increase in health claims for these products, the total number of ads for them has fallen considerably and the absolute percentage of ads with such claims remains relatively small (14% in 1997). In addition, almost all of the health claims were made for only one product - orange juice - and so consumers may not be receiving information about the health implications of consuming many other fruits, vegetables, and juices.

111. For instance, among the ads reviewed, there were no post-NLEA health claims for meat products, breads, salad dressings, and cooking oils, including reduced fat or non-fat brands of these products.

112. NLEA labeling regulations prohibit health claims in labeling for any food that does not meet specific nutrient thresholds, including foods that contain too much total fat. Cooking oils and most margarine would exceed the total fat content and thus not qualify for a health claim in labeling.

113. A. Mathios, The Importance of Nutrition Labeling and Health Claim Regulation on Product Choice: An Analysis of the Cooking Oils Market, Agric. & Resource Econ. Rev. 27 (1998).

114. In some circumstances, it is possible that labeling claims could be a substitute for advertising claims. As discussed above, the NLEA mandates the disclosure of certain information on food labels. *See supra* note 101. We are not aware of any empirical evidence addressing whether food advertising claims have decreased because this information now appears on food labels.

115. 64 Fed. Reg. 62,746, 62,754-55 (Nov. 19, 1999). Indeed, a new report by the National Academy of Sciences concludes that trans fatty acids may elevate harmful cholesterol (low-density lipoprotein) even more than saturated fat does. "Letter Report on Dietary Reference Intakes for Trans Fatty Acids" Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids, A Report of the Panel on Macronutrients, Subcommittee on Upper Reference Levels of Nutrients and on Interpretation and Uses of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Institute of Medicine, July 2002.

116. *See Comment of the Staff of the Bureau of Economics and Consumer Protection of the Federal Trade Commission in the matter of Trans Fatty Acid in Nutrition Labeling*, Docket No. 94P0036 (Apr. 17, 2000). The staff believes that even greater consumer benefits could be realized if FDA were to expand its proposal to allow specific health claims explaining the likely link between trans fatty acids and heart disease. The FTC staff comment also suggested that FDA might wish to consider authorizing a descriptor for “Reduced Trans Fat.” Among other benefits, this descriptor would aid the competitive process by providing an incentive for manufacturers to reduce the trans fatty acid content of foods where completely eliminating it would be difficult.

117. “Help-seeking” advertisements encourage consumers to talk to their doctors about health conditions without mentioning a specific drug treatment. “Reminder” advertisements identify specific drugs, but not the drug’s indications. Help-seeking ads and reminder ads faced less onerous disclosure requirements, and were fairly common. Consumers, however, often found such ads confusing. *See* Tamar Nordenberg, “Direct to You: TV Drug Ads That Make Sense:” *FDA Consumer Magazine*, Jan.-Feb. 1998, <http://www.fda.gov/fdac/features/1998/198_ads.html>.

118. Before the Department of Health and Human Services, Food and Drug Administration, In the Matter of Direct-to-Consumer Promotion; Public Hearing Docket No. 95N-0227, Comments of the Staff of the Bureau of Consumer Protection and the Bureau of Economics of the Federal Trade Commission, January 11, 1996.

118. U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, “Attitudes and Behaviors Associated with Direct-to-Consumer (DTC) Promotion of Prescription Drugs: Main Survey Results,” 1999, <www.fda.gov/cder/ddmac/dtcindex.htm> and Katheryn J. Aikin, “Direct-to-Consumer Advertising of Prescription Drugs: Preliminary Survey Results,” Division of Drug Marketing, Advertising and Communications, Food and Drug Administration, Apr. 18, 2002.

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120. The Henry J. Kaiser Family Foundation, “Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising,” Nov. 2001.

121. John E. Calfee, “Public Policy Issues in Direct-to-consumer Advertising of Prescription Drugs,” American Enterprise Institute, Washington, D.C., July 1, 2002.

123. Prevention, “*Fifth Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines*”¹²³.

the 15 per cent or more annual increases in drug spending over the past several years may be partly attributable to increases in DTC advertising. *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, National Institute for Health Care Management Research and Educational Foundation (NIHCM), Revised May 6, 2002, Washington, DC, <<http://www.nihcm.org>>. Other studies, however, suggest that DTC advertising is so small relative to total drug expenditures (about 2% of total sales) that it is unlikely to have a significant impact. See Richard Manning and Alison Keith, "The Economics of Direct-to-Consumer Advertising of Prescription Drugs," in *Economic Realities in Health Care Policy: Prescription Drug Advertising: Empowering Consumer Through Information*," June, 2001, 49" in