

**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\***

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**\*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.**

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## I. INTRODUCTION

The Food and Drug Administration (“FDA”) has requested comment<sup>1</sup> on a broad range of issues relating to whether its regulations, guidances, policies, and practices continue to comply with governing First Amendment case law following the Supreme Court’s recent decision in *Thompson v. Western States Medical Center*.<sup>2</sup> Specifically, the agency is seeking guidance on how it can fulfill its mandate to protect consumer health and safety in a manner consistent with the commercial speech doctrine, which provides First Amendment protection to truthful and non-misleading claims made in advertising, labeling, and other forms of marketing. The staffs of the Bureau of Consumer Protection, Bureau of Economics, and Office of Policy Planning of the Federal Trade Commission (the “FTC staff” or “Commission staff”) offer the following comment to assist the FDA in its deliberations on these important and timely issues.

This comment does not opine on the constitutionality of any specific FDA statute, regulation, policy, or practice, or suggest revisions to FDA’s regulatory framework. Moreover, recognizing the differences between the FDA’s public health mandate to ensure the safety and efficacy of drugs and other products and the FTC’s mandate to prevent deceptive, misleading, or unsubstantiated claims, this comment does not address the substantive standards used by FDA to determine whether to allow the sale of products. Rather, the FTC’s experience is relevant to the marketing and advertising claims made for products already approved for sale. This comment sets out the FTC’s enforcement approach, which reflects the principles embodied in the commercial speech doctrine. The comment also discusses empirical research findings which suggest that enforcement approaches seeking to maximize the free flow of commercial speech promote consumer welfare as well as survive constitutional challenge. More specifically, the

views of FTC staff can be summarized in the following points:

- In executing our mission, we have found that the First Amendment commercial speech doctrine is fully compatible with our vigorous consumer protection program. The FTC requires that all claims be true, non-misleading, and substantiated at the time they are made. The FTC's post-market review of advertising claims and application of tailored remedies in advertising cases curb deception without overly restricting truthful commercial speech, thus promoting the goals embodied in the First Amendment.<sup>3</sup>
- The FTC's approach to advertising for products like foods, over-the-counter ("OTC") drugs, and dietary supplements, while generally consistent with that of the FDA for these products, is also understandably more flexible, allowing a broader range of claims so long as they are accurate and not misleading. The Commission's law enforcement approach seeks to ensure that products and services are marketed in a manner that is truthful and not misleading, and that consumers have adequate information to make well-informed purchasing decisions.
- In practice, consumer protection agencies must often 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. In making these decisions, the Commission's approach takes account of the sensitivity of certain kinds of claims. For example, the Commission has particularly rigorous substantiation requirements for health and safety claims. The Commission recognizes, of course, that even these rigorous standards require vigorous 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 misleading claims when they occur, produces benefits for consumers.

- Striking the right balance depends on the nature of the claims and the risks that result from deception. Applicable First Amendment law looks in part to the availability of less restrictive alternatives, such as mandated disclosures, in assessing the legality of outright bans on potentially misleading commercial speech.
- Although disclosures can qualify claims in many instances, there are also limitations to their use. For example, accurate information in the text may not remedy a false headline; fine print written disclosures may be insufficient to correct a misleading representation; other practices of the company may direct consumers' attention away from the qualifying disclosures; and *pro forma* statements or disclaimers may not cure otherwise deceptive messages or practices.<sup>4</sup> Disclosures are most effective if they are clear and prominent, 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.
- Empirical evidence suggests that if consumers receive more and better information about nutrition and health, consumers are able to make better-informed choices about the food products they purchase. This, in turn, creates economic incentives for companies to develop healthier food products to satisfy consumers. Consumers thus would benefit if the FDA expanded its use of regulatory approaches that allow the dissemination of truthful and non-misleading claims about the nutrient content and health benefits of foods, such as in the trans fatty acid example described below.

- 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.”<sup>5</sup> 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.”<sup>6</sup>

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.<sup>7</sup> 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*,<sup>8</sup> the Supreme Court held that commercial speech, including most advertising and labeling,<sup>9</sup> was entitled to protection under the First Amendment. In that case, Virginia had enacted a statute that declared that it was professional misconduct for any pharmacist to advertise the price of prescription drugs. A consumer and two non-profit organizations challenged the statute, arguing that they had a First Amendment right to receive price information about drugs and that pharmacists had a First Amendment right to provide them with this information. After a three-judge district court panel declared the statute unconstitutional, Virginia appealed directly to the U.S. Supreme Court. The Court articulated the issue to be decided in the case as whether the First Amendment protected the pharmacists' right to communicate "I will sell you X prescription drug at Y price."

The Court concluded that the First Amendment does protect such commercial speech because of its value to consumers<sup>10</sup> and competition<sup>11</sup> in a free market economy:

Advertising . . . is . . . dissemination of information as to who is producing and selling what product, for what reason, and at what price. \* \* \* It is a matter of public interest that [private] economic decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is 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.<sup>12</sup>

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*,<sup>13</sup> 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.”<sup>14</sup> Third, if it is substantial, the court “must determine whether the regulation directly advances the governmental interest asserted.”<sup>15</sup> Fourth, the court must determine “whether [the regulation] is not more extensive than is necessary to serve that interest.”<sup>16</sup> To survive a First Amendment challenge, the government has the burden of proving that its restriction on commercial speech satisfies the *Central Hudson* test.<sup>17</sup>

### **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*,<sup>18</sup> 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.<sup>19</sup> 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."<sup>20</sup> 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.<sup>21</sup> 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.<sup>22</sup>

The court explained that the First Amendment commercial speech doctrine embodies a "preference for disclosure over outright suppression."<sup>23</sup> 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."<sup>24</sup> 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.<sup>25</sup> 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,”<sup>26</sup> 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,”<sup>27</sup> 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.<sup>28</sup> 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.

### **C. Fundamental Principles**

Over the past twenty-five years, commercial speech jurisprudence, including the recent cases involving FDA regulation of claims for drugs and dietary supplements, has established certain fundamental principles. Among the most important for the government to consider in deciding whether possible approaches to regulating commercial speech are consistent with the First Amendment are the following:

- (1) The free flow of truthful and non-misleading commercial speech empowers consumers to make better-informed purchasing decisions and maximizes consumer welfare.<sup>29</sup>
- (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.<sup>30</sup>

- (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.<sup>31</sup>

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.”<sup>32</sup>

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

(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.”<sup>34</sup>

(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.<sup>35</sup> However, if a potentially misleading claim is “incurable by disclaimer [the government can] ban it outright.”<sup>36</sup>

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 out to be false, misleading, or unsubstantiated and the risk of banning commercial speech that could turn out to be truthful, not misleading, and substantiated.<sup>37</sup> Making such a choice requires a careful determination of exactly what claims are being conveyed and whether they can be effectively qualified. (A description of the efficacy of FTC disclosure requirements is set forth below at pages 15-16 and 19-20). It also requires a thorough review of the sometimes complex or novel scientific evidence to determine whether the claims are supported. As discussed in the following section, we believe that the FTC’s approach to

advertising regulation - that is, relying primarily on post-dissemination, case-by-case law enforcement challenges - is a consumer protection model that comports with the First Amendment and properly balances the risks under the laws that the Commission enforces.

### **III. THE FTC ENFORCEMENT APPROACH**

The FTC and the FDA share jurisdiction over the marketing of various health-related products. Under the terms of a long-standing liaison agreement governing the division of responsibilities, the FDA exercises primary responsibility for regulating the labeling of foods, dietary supplements, over-the-counter drugs, cosmetics, and medical devices. The FTC has primary responsibility for regulating the advertising of these products.<sup>38</sup> The liaison agreement also provides that the FDA has primary responsibility for both the labeling and advertising of prescription drugs.<sup>39</sup>

The FDA's approach to regulating these products frequently relies on prior approval. The Food, Drug, and Cosmetic Act prohibits the introduction of a new drug into interstate commerce unless an application demonstrating the drug's safety and efficacy has been approved by the FDA.<sup>40</sup> The law also requires pre-market approval of certain categories of claims. For example, the FDA pre-approves health claims for food labels<sup>41</sup> and dietary supplement labels.<sup>42</sup> Further, although the FDA does not 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.<sup>43</sup>

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.<sup>44</sup> 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.<sup>45</sup> The FTC imposes targeted remedies to stop deception; it does not require broad pre-market approval of categories of claims,<sup>46</sup> 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.<sup>47</sup>

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,<sup>48</sup> dietary supplements,<sup>49</sup> over-the-counter drugs<sup>50</sup> and medical devices.<sup>51</sup> 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.<sup>52</sup> 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.<sup>53</sup>

## **A. Legal Framework**

The Commission's authority derives from Section 5 of the Federal Trade Commission Act ("FTC Act"), which broadly prohibits "unfair methods of competition and deceptive or unfair acts or practices in or affecting commerce."<sup>54</sup> In addition to Section 5, Section 12 of the FTC Act more specifically prohibits the dissemination of false advertisements for foods, drugs, devices or cosmetics.<sup>55</sup> One of the agency's principal responsibilities under Sections 5 and 12 of the FTC Act is to police claims made in national advertising. In implementing its advertising program, the Commission relies principally on its authority to prevent deceptive practices.<sup>56</sup> A deceptive ad is one that contains a material misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment. The FTC's objective in these cases is to ensure that consumers receive accurate information so that they can make well-informed decisions.

## **B. The Deception Analysis**

Bringing an enforcement action against a deceptive ad under the FTC Act involves three basic inquiries. The Commission must determine: (1) what express and implied claims an ad conveys, (2) whether the claims are false or unsubstantiated, and (3) whether the claims are material to consumers.<sup>57</sup> Substantiation for health claims must consist of competent and reliable scientific evidence.<sup>58</sup>

### **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.<sup>59</sup> 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.<sup>60</sup> 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.<sup>61</sup>

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.<sup>62</sup> Advertising may also be deceptive by simply remaining silent, if doing so communicates an implied, false representation.<sup>63</sup> 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.<sup>64</sup>

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.<sup>65</sup> 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.<sup>66</sup>

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.<sup>67</sup> 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.<sup>68</sup>

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.<sup>69</sup> The Food Copy Test appears to confirm that claims involving complicated scientific concepts require careful and detailed qualification.<sup>70</sup> 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.<sup>71</sup> 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 FDA may determine, consistent with its mission, that certain claims cannot be adequately qualified.

## **2. Evaluating Claim Substantiation**

The second inquiry in an FTC enforcement action is to assess whether the identified claims are truthful and adequately substantiated. As noted above, health claims must be supported by competent and reliable scientific evidence. Some claims are outright false and therefore are deceptive.<sup>72</sup> Other claims are challenged by the FTC because they are unsubstantiated. The advertiser must have a reasonable basis for any objective product claim when it is made.<sup>73</sup> FTC law provides for substantial flexibility as to what constitutes a reasonable basis. How a claim is presented and qualified drives the standard. If, for instance, the ad contains an express or implied representation regarding the amount of support the advertiser has for the claim, the Commission expects the advertiser to have at least the level of support claimed in the ad.<sup>74</sup> Claims that are more clearly qualified to reflect more limited support would therefore require less substantiation than an unqualified claim. If there is no characterization of the evidence, the Commission will consider a number of factors to determine the appropriate level of support for a claim.<sup>75</sup> These factors include the type of product, the type of claim, the benefits of a truthful claim, the cost and feasibility of developing substantiation, the consequences of a false claim, and the amount of substantiation that experts in the field believe is reasonable.<sup>76</sup>

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.”<sup>77</sup> 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.<sup>78</sup>

### **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.<sup>79</sup> Many claims are presumptively material, such as express claims, health claims, and safety claims.<sup>80</sup> 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,<sup>81</sup> (2) that the advertised product sold at a price premium compared to its competitors,<sup>82</sup> (3) the advertiser’s own assessment of the success of its claims,<sup>83</sup> or (4) a correlation between the dissemination of the claims and increased sales of the advertised product.<sup>84</sup>

### **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."<sup>85</sup> The Supreme Court has consistently held that government may ban false or misleading advertising claims. Such claims are entitled to no First Amendment protection.<sup>86</sup>

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 advertiser will not engage in similar deceptive practices with impunity.<sup>87</sup> Because such fencing-in relief bans advertising claims that are themselves false or misleading, it does not trigger First Amendment protection and has been routinely upheld by the courts.<sup>88</sup>

The Commission will also impose information remedies in its orders when additional facts need to be disclosed to prevent an ad from conveying a deceptive impression<sup>89</sup> or, on rare occasion, when the disclosure of information is needed to correct a lingering misimpression created by a prior deceptive advertising campaign. The Commission has a long history of favoring disclosures over outright bans where such disclosures are a viable means to protect consumers from deceptive speech.<sup>90</sup> It is well established that the government may “require that a commercial message appear in such a form, or to include such additional information, warnings, and disclaimers, as are necessary to prevent deception.”<sup>91</sup> Not only is such an approach consistent with the First Amendment,<sup>92</sup> the courts have routinely found it to be the preferred approach to curing deceptive speech.<sup>93</sup> In crafting required disclosures, the Commission is careful to ensure that they are not overly burdensome and do not exceed what is necessary and appropriate to remedy the deception. This approach minimizes the restriction on truthful speech, and recognizes that the courts have indicated that disclosure requirements may still violate the First Amendment if they are “unjustified or unduly burdensome.”<sup>94</sup> The particular mission of the government agency imposing the disclosure requirement may affect whether a court determines that the restriction at issue meets this standard.

Corrective advertising is another remedy the Commission may impose in appropriate cases. It requires the advertiser to include an affirmative statement in future advertising to correct a false belief that was either created or reinforced by the challenged advertising. The Commission will impose such a 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.<sup>95</sup>

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 product<sup>96</sup> or it may require that information be presented in a standardized format that allows consumers to better compare products or services.<sup>97</sup> 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.<sup>98</sup>

The FTC staff believes that our experience using these types of remedies to protect consumers from deceptive or unfair advertising<sup>99</sup> may be helpful to the FDA as it considers its own approach. The FTC’s remedies are carefully targeted to stop deceptive speech, to disclose facts necessary to prevent claims from being deceptive, and to correct lingering deceptive impressions. An approach that focuses on deceptive speech, favors requiring more information over banning information, and avoids broad restrictions limiting both deceptive and non-deceptive speech is more likely to survive constitutional challenge.

#### **IV. EMPIRICAL EVIDENCE ON APPROACHES TO COMMERCIAL SPEECH**

The available empirical evidence on advertising and labeling of foods and drugs reveals the 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 advertising and labeling can also provide a strong incentive to competitors to develop new products and to improve existing products, giving consumers more and better choices.

There have been a number of changes over the years in the FDA's policies and regulatory framework for foods and drugs. These changes have provided the opportunity to examine the impact on consumers and competition of both more and less restrictive approaches to information in labeling and advertising. A few of the key findings on how regulatory policies have affected the flow of information about the risks and benefits of foods and drugs are described below. The FTC staff believes that this empirical evidence will assist the FDA in the current review of its policies, by illustrating how the agency can tailor its regulatory approach to improve the flow of important health information to consumers consistent with First Amendment

principles.

### **A. Food Advertising**

Truthful and non-misleading claims in food advertising and labeling<sup>100</sup> can play a vital role in fostering well-informed consumer dietary choices and in encouraging food marketers to develop and offer healthier products. The government and other general information sources usually disseminate educational material concerning the relationship between diet and health or the health benefits of changing one's dietary intake of various nutrients. In addition to government-mandated disclosures,<sup>101</sup> food marketers often decide to disseminate specific information on labels and in advertising concerning the presence and significance of nutrients in a particular brand of food product. Consequently, government efforts and truthful commercial speech about the health effects of food often complement one another,<sup>102</sup> maximizing the information consumers receive in deciding which foods to purchase.<sup>103</sup>

If food marketers make health and nutrient content claims for their products, consumers will become more aware of the significance of the nutrients in foods and will learn to consult the nutrition facts panels to obtain more information about them. As consumers become interested in purchasing more nutritious products, food marketers are given a powerful economic incentive to develop and market healthier products.<sup>104</sup> Comparative advertising among food marketers, in particular, often highlights why one brand is more nutritious than a competing brand. Such continuous marketing creates competitive pressure on companies to make their food products more and more nutritious.

Three examples illustrate the significant benefits that flow from the dissemination of nutrient and 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.<sup>105</sup> 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,<sup>106</sup> and more high-fiber cereal products were introduced into the market.<sup>107</sup> 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.<sup>108</sup> 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 Report<sup>109</sup> 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.<sup>110</sup>

At the same time, however, there now appear to be very few health claims in advertising

for many other types of foods.<sup>111</sup> 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.<sup>112</sup> 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.<sup>113</sup> 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.<sup>114</sup>

### **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.<sup>115</sup> 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 foods. The experience with fiber/cancer and fat/heart disease claims, discussed above, indicates that allowing trans fatty acid information is likely to provide the additional benefit of stimulating competition among food manufacturers to develop new products that do not contain trans fatty acids.<sup>116</sup> It may be that FDA's proposed rule on trans fatty acid claims could serve as a model to follow in allowing other categories of claims that could provide similar health benefits.

### **B. Direct-to-Consumer Advertising of Prescription Drugs**

The history of the FDA's policy regarding DTC advertising demonstrates an evolution toward a regulatory approach that recognizes the value of commercial speech to consumers. As with food labeling and advertising, empirical evidence suggests that the FDA's current more flexible approach to information regulation is conferring some benefits on consumers.

The FDA's policy toward DTC advertising has been evolving since the early 1980s, when some advertisers started to introduce prescription drug advertisements for consumers. In 1982, the FDA asked the industry for a moratorium on DTC advertising while it considered an appropriate policy response. The moratorium was lifted in 1985. Manufacturers understood that DTC advertisements would be allowed, but they would require a "fair balance" of information, as well as extensive disclosures of drug effectiveness, contraindications, and side effects (the "brief summary"). Even with these restrictions, DTC advertising grew, although broadcast advertisements were typically limited to "help seeking" or "reminder" advertisements due to extensive disclosure requirements.<sup>117</sup>

In 1996, when the FDA proposed its current less-restrictive approach to broadcast 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.”<sup>118</sup> 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,<sup>119</sup> Prevention (2001/2002),<sup>120</sup> and the Henry J. Kaiser Family Foundation (2001).<sup>121</sup> Details of these surveys are discussed extensively in Calfee (2002).<sup>122</sup>

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.<sup>123</sup>

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.”<sup>124</sup>

Consumer surveys also suggest that DTC advertising has not harmed the doctor-patient relationship. Many consumers who were part of a survey that the FDA conducted in 2002 reported asking their doctors about a drug to treat a condition or about a specific brand (23% and 7% respectively) after seeing a DTC advertisement. Consumers who asked their doctors about a particular drug said that their doctors reacted well when they asked about particular drugs to treat a condition: 93% reported that the doctor welcomed the question, and only 3% reported that the doctor was angry or upset.

The 2001/2002 Prevention magazine survey also examined the effect of DTC advertising on the doctor-patient relationship. According to the survey:

From the consumer perspective, doctors are very willing to talk with them about advertised medicines, and many consumers believe these conversations have improved their relationships with their doctors. Seventy-nine percent of consumers who asked their doctors about an advertised medicine say their doctors were *very* willing to answer questions and additional 16 percent say their doctors were somewhat willing.<sup>125</sup>

Perhaps even more telling is that 27 percent of patients who spoke with their doctors about an advertised medication said that the discussion improved their relationship with their doctor, while only 1 percent said it harmed their relationship.<sup>126</sup> 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.<sup>127</sup> 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.<sup>128</sup> 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.<sup>129</sup> 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,<sup>130</sup> and remains small relative to expenditures on professional marketing (such as detailing and free sampling).<sup>131</sup> 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 professionals reinforces the conventional wisdom that physicians are unlikely to prescribe a drug unless they are familiar with it and are comfortable prescribing it. It may thus be accurate to characterize direct-to-consumer advertising as a marketing strategy that complements rather than displaces promotional efforts targeted at professionals, especially in the case of indications for which alternative therapies exist.<sup>132</sup>

Moreover, although total spending on all forms of drug promotion has increased by roughly 70 percent between 1996 and 2000, it has remained fairly constant at 14 to 15 percent of product sales.

In short, the evidence currently available suggests that DTC advertising has had positive effects. DTC advertising appears to prompt consumers to seek out information about medications and medical conditions, some of which may not have been diagnosed previously. The information that consumers acquire may allow them to have enhanced conversations with their doctors about treatment options and may permit them to make better-informed health care decisions for themselves. The cost of providing the information appears to be low. Definitive conclusions regarding the precise nature of the impact of the FDA's current approach to DTC advertising on consumer welfare cannot be reached, however, until better empirical evidence is developed concerning its effects on drug expenditures<sup>133</sup> and health outcomes.<sup>134</sup>

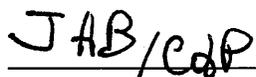
## V. CONCLUSION

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.

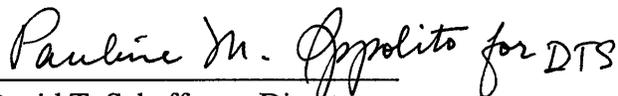
The commercial speech doctrine recognizes the importance of consumer access to truthful and accurate information. On the other hand, inaccurate or misleading claims have no protection under the First Amendment and need to be purged from the marketplace to protect and enhance the value of the free flow 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.

Respectfully submitted,



J. Howard Beales III, Director  
Thomas B. Pahl, Assistant Director, Division of Advertising Practices  
Bureau of Consumer Protection



David T. Scheffman, Director  
Dennis Murphy, Economist  
Janis K. Pappalardo, Economist  
Bureau of Economics



Ted Cruz, Director  
Maureen K. Ohlhausen, Attorney  
Office of Policy Planning

## Endnotes

1. Department of Health and Human Services, Food and Drug Administration, *Request for Comment on First Amendment Issues*, 67 Fed. Reg. 34,942 (May 16, 2002).
2. 535 U.S. \_\_\_\_, No. 01-344 (Apr. 29, 2002).
3. The FTC has been largely successful in curbing deception in the marketplace in a manner consistent with the First Amendment commercial speech doctrine. Since the Supreme Court articulated its standard for analyzing the constitutionality of restrictions on commercial speech more than two decades ago, only one limited provision of one advertising orders has been found to violate the First Amendment. See *FTC. v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 45 (D.C. Cir. 1985).
4. Deception Policy Statement, appended to *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 176 n.7 (1984)
5. *Request for Comment on First Amendment Issues*, 67 Fed. Reg. at 34,943.

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.*

17. *Id.*
18. 164 F. 3d 650 (D.C. Cir. 1999), *reh'g en banc denied*, 172 F.3d 72 (D.C. Cir.1999).
19. *Id.* at 655.
20. *Id.*
21. *Id.* at 655-56.
22. *Id.* at 657.
23. *Id.* at 658.
24. *Id.*
25. *Western States Med. Ctr.*, slip op. at 11-13.
26. *Id.* at 13.
27. *Id.*
28. *Id.* at 14.
29. *Virginia Bd. of Pharmacy*, 425 U.S. at 765.
30. *Central Hudson*, 447 U.S. at 566; *In re R.M.J.*, 455 U.S. 191, 200 (1982) (“False, deceptive, or misleading advertising remains subject to restraint”).
31. *Central Hudson*, 447 U.S. at 566.
32. *Western States Med. Ctr.*, slip op. at 9 (rejecting argument that truthful and non-misleading commercial speech for compounded drugs may be prohibited because it may cause consumers to purchase drugs they do not need); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 375 (1977) (“We view as dubious any justification that is based on the benefits of public ignorance.”); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 70 (D.D.C. 1998) (“To endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection, which is the gravamen of the FDA’s claim here, is practically an engraved invitation to have the restriction struck.”).
33. *See, e.g., Edenfield v. Fane*, 507 U.S. 761, 769 (1993) (“[T]here is no question that [the government’s interest] in ensuring the accuracy of information in the marketplace is substantial.”).
34. *See Board of Trustees of the State of New York v. Fox*, 492 U.S. 469, 480 (1989).

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).

42. Health claims for dietary supplements are subject to the same pre-authorization requirement as health claims for foods. Other claims, such as those about the role of a supplement in supporting the normal structure of function of the body, are exempt from this pre-authorization requirement. 21 U.S.C. § 343(r)(6).

43. 21 C.F.R. § 202.1(j).

44. The Commission also uses a variety of other means to identify and prevent deceptive advertising claims, such as legislative rules, interpretive rules, guides, policy statements, informal business guidance, and public workshops.

45. As an example, the FTC's Enforcement Policy Statement on Food Advertising indicates that certain comparative nutrient claims (e.g., "less fat"), prohibited under FDA labeling regulations, may be permissible under Section 5 of the FTC Act as long as they are accurately qualified to avoid any misleading implications about the basis for the comparison or its significance. 59 Fed. Reg. 28,388 (June 1, 1994) (Food Policy Statement) at Section III. A.2. Similarly, both the Food Policy Statement and the FTC's "Dietary Supplements: An Advertising Guide for Industry" provide some leeway for advertising claims about the health benefits of foods and supplements that may not have been specifically approved for labeling under FDA's significant scientific agreement standard. This greater leeway for health claims in advertising, however, is limited to benefits that are supported by strong emerging science and to claims that are carefully qualified to reflect any limitations or uncertainty in the science. See Food Policy Statement at Section IV.A.; Dietary Supplements: An Advertising Guide for Industry, FTC, Bureau of Consumer Protection (1998)(Supplement Guide) at Introduction.

46. In limited circumstances, the Commission has banned some types of claims. For example, the FTC's Telemarketing Sales Rule prohibits telemarketers from receiving or requesting an advance fee for obtaining a loan when they have "guaranteed or represented a high likelihood of success in obtaining or arranging a loan or other extension of credit for a person." 16 C.F.R. § 310(a)(4).

47. Since the Supreme Court articulated its standard for analyzing the constitutionality of restrictions on commercial speech more than two decades ago, only one limited provision of one advertising order has been found to violate the First Amendment. See *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 45 (D.C. Cir. 1985).

48. See, e.g., *Interstate Bakeries Corp.*, C-4042 (Mar. 6, 2002) (consent) (brain function and memory claims for Wonderbread); *Conopco, Inc.* C-3706 (Jan. 23, 1997) (consent) (heart health claims for Promise margarines); *Egglund's Best, Inc.*, C-3520 (Aug. 15, 1994) (consent) (effect of eggs on serum cholesterol); *Stouffer Foods Corp.*, D. 9250 (Sept. 26, 1994 (Commission Decision) (sodium content of Lean cuisine frozen entrees); *Campbell Soup Co.*, 115 F.T.C. 788 (1992) (consent) (heart health claims for soup with high sodium content).

49. See, e.g., *Kris A. Pletschke d/b/a Raw Health*, C-4040 (Feb. 22, 2002) (consent) (challenging claims for colloidal silver as treatment cure for 650 diseases, including anthrax); *Natural*

*Organics, 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 enforcement initiative, the FTC launches a comprehensive and creative education campaign. In addition, the Commission often obtains redress for injured consumers. For example, from May 2001 to April 2002, the Commission obtained judgments ordering more than \$97 million in consumer redress.

54. 15 U.S.C. § 45.

55. 15 U.S.C. §§ 45, 52. Under Section 15 of the Act, a "false advertisement" is defined as one that is misleading in a material respect. 15 U.S.C. § 55.

56. Although the vast majority of the FTC's advertising cases target deception, the Commission can also challenge advertising claims under its unfairness jurisdiction. An unfair practice is one that causes, 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 meaning any ad that is "misleading in a material respect," and directs that, "in determining whether any advertisement is misleading, there shall be taken into account \* \* \* the extent to which the advertisement fails to reveal facts material in light of [the] representations [made] or material with respect to consequences which may result from the use of the commodity to which the advertisement relates." As an example, in the Campbell Soup case the FTC challenged a claim that the soup was low in fat and cholesterol and therefore heart healthy as deceptive because the ad did not disclose that the soup was high in sodium, a risk factor for hypertension. *See Campbell Soup Co.*, 115 F.T.C. 788 (1992) (consent). The FTC has also found the omission of information about significant safety concerns relating to a product in an ad making affirmative safety claims to be deceptive under Commission law. *See, e.g., Panda Herbal Int'l, Inc.*, C-4018 (July 30, 2001) (consent) (challenging claims that St. John's Wort supplement had no contraindications or drug interactions).

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 (7<sup>th</sup> 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 (4<sup>th</sup> 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).

68. As one example, information intended to disclose high levels of an undesirable nutrient like saturated fat, often led consumers to believe instead that the food had low or healthy levels of the nutrient. An explicit verbal disclosure stating that the product was high in saturated fat, and that high levels of saturated fat intake increase the risk of heart disease, successfully corrected this misimpression. The results of the Food Copy Test are consistent with the results of a copy test the FTC staff conducted in 1993 of ads with qualifying disclosures to limit the scope of environmental claims. T. Maronick & C. Andrews, The Role of Qualifying Language on Consumer Perception of Environmental Claims, J. Consumer Aff. (Winter 1994).

69. See Food Copy Test at Part V. At the same time, it should be noted that the Food Copy Test also provides some indication that consumers tend to approach health claims, even those presented in the most absolute terms as scientifically proven, with some skepticism.

70. Not only does this type of information involve highly technical nuances that may be beyond the expertise of the consumer, but also research shows that there are limits to the amount of information consumers can assimilate and recall from advertising. See, e.g., J. Richards, Deceptive Advertising: Behavioral Study of a Legal Concept (1990) at 112-113 (showing low consumer recall of elements of print and television ads).

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 U.S. Medical Schools," and "extensive research at prestigious institutions," which the Commission's complaint charged constituted a claim that the product had been "tested and scientifically validated by reputable universities and medical institutions."

75. As discussed above, regulators often confront great uncertainty in choosing between the risks of making a Type I error (allowing a deceptive claim) or a Type II error (prohibiting a non-deceptive claim) with regard to commercial speech. *See* note 37, *supra*. The FTC's approach of weighing a number of factors in determining whether there is a "reasonable basis" for an advertising claim is beneficial because it requires that the government engage in an explicit consideration of the trade-offs between Type I and Type II errors with regard to commercial speech. 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 35 (1989).

76. Substantiation Statement at 840. The Commission first articulated these factors in *Pfizer, Inc.*, 81 F.T.C. 23 (1972).

77. *See, e.g., Schering Corp., 118 F.T.C. 1030* (1994) (consent) (challenging unsubstantiated weight loss claims for Fibre Trim supplement); *Interstate Bakeries Corp., C-4042* (2002) (consent) (challenging unsubstantiated brain function and memory claims for Wonderbread); *Pfizer, Inc., C-3841* (1998) (consent) (challenging unsubstantiated efficacy claims for head lice treatment).

78. The FTC does not impose any fixed formula as to the number or type of studies required to meet the competent and reliable scientific evidence standard, or any specific parameters for

sample size and study duration. Instead, it provides a few simple principles that ensure the science is of good quality 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 prohibit government regulation of false or misleading speech.”).

87. *See, e.g., Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612 (1946); *see also FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952) (“[the FTC] cannot be required to confine its road block to the narrow lane the transgressor has traveled; it must be allowed effectively to close all the roads to the

prohibited goal, so that its order may not be by-passed with impunity.”).

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: “the free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful.” *Shapiro v. Kentucky Bar Ass'n*, 486 U.S. 466, 478 (1987) (quoting *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985)).

90. The Commission uses bans when the speech itself is inherently deceptive. For example, the Commission has sometimes banned the use of trade names that are deceptive and cannot be qualified without resulting in a confusing contradiction in terms. See, e.g., *Brake Guard Prods., Inc.*, 125 F.T.C. 138, 252-53 (1998), *aff'd sub nom. Jones v. FTC*, 194 F.3d 1317 (9th Cir. 1999); *Resort Car Rental System, Inc. v. FTC*, 518 F.2d 962, 964 (9th Cir. 1975) (affirming FTC order prohibiting use of trade name “Dollar-A-Day” in connection with rental car agency); *Continental Wax Corp. v. FTC*, 330 F.2d 475, 479-80 (2d Cir. 1964) (upholding the excision of the “Six Month” portion of the trade name “Six Month Floor Wax”). The Commission uses bans when a defendant's course of conduct demonstrates such a propensity for future deception that a ban is necessary to protect consumers, e.g., banning a telemarketer from engaging in telemarketing when he has engaged in telemarketing fraud in the past.

91. *Virginia Bd. of Pharmacy*, 425 U.S. at 771-72 n. 24.

92. In *Zauderer*, for example, the Supreme Court upheld the constitutionality of a disclosure explaining that the lawyer's claim that clients would not have to pay any “legal fees” did not encompass certain costs that would be charged to the client. The Court stated that “warning[s] or disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception. 471 U.S. at 651 (quoting *In re R.M.J.*, 455 U.S. at 201).

93. See, e.g., *Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 110 (1990) (explaining that, under the First Amendment, “the preferred remedy is more disclosure rather than less”); see also *In re R.M.J.*, 455 U.S. at 206, n.20; *Shapiro v. Kentucky Bar Ass'n*, 486 U.S. 466, 478. This was also the cornerstone of the Court's ruling in the *Pearson* case, as discussed above, where FDA's prohibition of certain health claims for dietary supplements was struck and the agency instructed to consider allowing qualified claims. 164 F.3d at 657.

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 (7<sup>th</sup> 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 (2<sup>nd</sup> 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 (2<sup>nd</sup> 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 facts information on the rear panel as being promotional in nature. *See J. Garretson & S. Burton, Effects of Nutrition Facts Panel Values, Nutrition Claims, and Health Claims on Consumer Attitudes, Perceptions of Disease-Related Risks, and Trust*, 19 J. Pub. Pol'y & Mktg. 213 (2000); M. Mazis & M. Raymond, Consumer Perceptions of Health Claims in

Advertisements and on Food Labels, 31 J. Consumer Aff. 10 (1997); A. Levy and B.M. Derby, The Impact of NLEA on Consumers: Recent Findings from FDA's Food Label and Nutrition Tracking System, Office of the Commissioner, Food 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 Bureaus 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](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](http://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.

119. The 2001/2002 Prevention survey, conducted with the technical assistance of FDA’s Division of Drug Marketing, Advertising, and Communication, “come from telephone interviews with a nationally representative sample of 1,601 adults who are ages 18 or older and are living in telephone households in the continental United States. Interviews were conducted by Princeton Survey Research Associates during the period of September 19 to October 7, 2001. The survey also includes an over sample of 1,000 men ages 18 or older. The data set is weighted so that the demographic parameters of this sample match the Census Bureau’s demographic parameters for the population under study. The margin of sampling error for the total 1,601-case sample is plus or minus 3 percentage points and plus or minus 4 percentage points for the 1,000-case over sample of men ages 18 or older.” Prevention, “A National Survey of Consumer Reactions to Direct-to-Consumer Advertising,” 1999 and Prevention, “International Survey on Wellness and Consumer Reactions to DTC Advertising of Rx Drugs,” 2000, and Prevention, “Fifth Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines” 2001/2002.

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" 2001/2002 at 3. This survey was developed with technical assistance from the FDA's Division of Drug Marketing, Advertising, and Communications. The survey results come from telephone interviews with a nationally representative sample of 1,601 adults, and interviews were conducted by Princeton Survey Research Associates.

124. *Id.* at 56.

125. *Id.* at 48.

126. *Id.*

127. National Medical Association, "Position Statement of the National Medical Association on Direct to Consumer Advertising," June 2002.

128. National Health Council, *Direct-to-Consumer Prescription Drug Advertising: Overview & Recommendations*, January 2002 at 12.

129. See Department of Health and Human Services, Food and Drug Administration, *Notice of Agency Information Collection Activities*, 66 Fed. Reg. 42,664 (Aug. 14, 2001).

130. Meredith B. Rosenthal, Ernst R. Berndt, Julie M. Donohue, Richard Frank, and Arnold M. Epstein, *Special Article: Promotion of Prescription Drugs to Consumers*, *New Eng. J. Med.* 346 (7), February 14, 2002, <<http://www.nejm.org>>. In 1996, DTC spending on television and print amounted to \$791 million (only 1.2 percent of overall sales). By 2000, DTC promotion had risen to \$2,467 million (only 2.2 percent of overall sales).

131. For example, in 1996, promotions to professionals totaled \$9,164 million (representing 14.1 percent of sales) and in 2000 promotions to professionals totaled \$15,708 million (14.0 percent of sales). *Id.* at 500.

132. *Id.* at 502.

133. There are no definitive studies establishing the exact impact of DTC advertising on drug expenditures. A recent National Institute for Health Care Management (NIHCM) study suggests that 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, Pfizer, Inc.; Rosenthal, et al., at 115. Other studies further suggest that increased drug expenditures are due to the complex interaction of many factors, such as how extensively a drug is promoted to professionals, whether it has preferential status with an insurer (i.e., it is listed on the formulary), and whether the advertising relates to a newly-approved use for a drug, and whether the supporting science is strong. See Pierre Azoulay, Do Pharmaceutical Sales Respond to Scientific Evidence? Evidence from Anti-ulcer Drugs (Sept. 8, 2001) (unpublished manuscript, Columbia Univ.)(studying promotions of prescription drugs to professionals); Marta Wosinska, Promoting to Multiple Agents: The Case of Direct-to-Consumer Drug Advertising, at 2 and 3 (Oct. 2001)(unpublished manuscript, Univ. of Cal. at Berkeley)(finding greater marginal impact from detailing than consumer advertising).

134. No definitive studies have been conducted as to the link between DTC advertising and improvements in the health of consumers. However, we note that even if a new drug for which DTC advertising is distributed is more expensive than an old drug, the additional expense may be justified because the new drug is a meaningful improvement over the old drug. See U.S. Dept. of Health and Human Services, Office of the Asst. Sec. for Planning and Evaluation, "Securing the Benefits of Medical Innovation for Seniors: The Role of Prescription Drugs and Drug Coverage," July, 2002, < <http://aspe.hhs.gov/health/reports/medicalinnovation/> at 1>. Moreover, such a new drug can only replace an old drug if a doctor (i.e., one with medical expertise) decides to write a prescription for the new drug because the doctor believes that it is better for a patient than the old drug.

## **Appendix One: Building a Record on Advertising Meaning and Substantiation**

The Commission has extensive experience in successfully challenging deceptive and unsubstantiated advertising and marketing claims without conflict with the First Amendment. This Appendix describes the process used to develop these cases.

In pursuing a formal law enforcement action, the Commission staff develops a record to establish, first, what claims are conveyed to consumers and, second, whether these claims are truthful and substantiated. Developing an adequate record, either for an administrative case or for federal court litigation, is critical to proving a violation of the FTC Act and ensuring that the enforcement action and remedies are consistent with the First Amendment.

### **A. Advertising Meaning**

In a deception-based law enforcement action, the first step is to determine what claims are conveyed and whether they are adequately qualified to avoid any misleading interpretation. To establish that an advertisement is deceptive, the Commission first must prove that the challenged advertising communicates a misleading claim to reasonable consumers.<sup>1</sup>

#### **1. Express Claims**

Proving that an ad makes an express claim – one that is literally stated in the advertising – requires no evidence beyond the text of the ad itself.<sup>2</sup> This is because the message is stated unequivocally, making it reasonable to interpret the ad as intending to make the claim.<sup>3</sup>

#### **2. Implied Claims**

Implied claims are not explicitly stated in the advertisement and range from those that use language and imagery "virtually synonymous with an express claim, through language that literally says one thing but strongly suggests another, to language which relatively few consumers would interpret as making a particular representation."<sup>4</sup> Depending upon the nature of the

implied claim, there are a number of means by which a record establishes the communication of an implied claim: (1) an analysis of the totality of the language and depictions of the ad itself, commonly referred to as a “facial analysis;” (2) extrinsic evidence in the form of marketing materials, general survey data or consumer survey evidence known as “copy tests;” and (3) extrinsic evidence provided by expert witnesses regarding what message or claim reasonable consumers are likely to take away from the ad.<sup>5</sup> These methods of proof have been used and upheld both in FTC administrative cases and in federal district court cases.

**a. Facial analysis**

It is well established that in appropriate cases, the advertisement itself may be used to establish an implied claim and the Commission need not resort to extrinsic evidence.<sup>6</sup> The Commission uses this approach when the language or depictions in the ad are clear enough to permit the court or other finder of fact to determine with confidence that the claim is conveyed to reasonable consumers.<sup>7</sup> When appropriate, the federal courts have consistently relied on facial analysis to interpret an ad and identify claims in FTC cases (although without necessarily explicitly referring to the approach).<sup>8</sup>

The preparation and presentation of a facial analysis to the Commission or a court can be relatively simple and brief. It involves an analysis of the advertisement as a whole. All of the elements of the ad - written, oral, and pictorial - and their likely interaction must be considered. Although one phrase or depiction may be central to claim communication, it is the net impression of all of the ad’s elements taken as a whole that must be analyzed in determining if reasonable consumers are likely to take a particular implied claim from the ad.<sup>9</sup>

A facial analysis is based upon a logical construction of an ad and is not necessarily

presented to a judge through a witness. Rather, it is presented through discussion in appropriate legal briefs. Used correctly, it is an inexpensive, simple, and effective method of proof. In the vast majority of FTC administrative cases and federal court cases, facial analysis is used to determine what implied claim or claims have been communicated to reasonable consumers. Courts have held that the First Amendment does not preclude the use of facial analysis to determine what claims are made when the claims are reasonably clear from the face of the ad.<sup>10</sup>

### **b. Copy Testing**

When a facial analysis cannot determine the claims conveyed with certainty, there are other sources the Commission or court will examine to discern the ad's meaning. The advertiser's intent as reflected in business records, marketing plans, or surveys can shed light on the claims communicated.

Many companies also undertake various forms of copy testing of proposed advertising prior to disseminating a final version.<sup>11</sup> This research can provide insight into claims communication. In a litigation or other fact finding proceeding, the Commission or the courts usually consider all copy test evidence proffered, including those conducted by an advertiser in the normal course of business.<sup>12</sup> The probative value of these studies varies. Those that use the forced exposure technique (asking questions immediately following exposure to the ad) are more likely to produce complete results than those that involve delayed recall (asking questions 24 to 72 hours after exposure to the ad).<sup>13</sup> In some cases, "normal course of business" copy tests do not use the full panoply of ad communication questions, particularly close-ended questions, which can limit their usefulness in determining claims communication.<sup>14</sup>

When the available extrinsic evidence is insufficient or flawed and the ad meaning is still

uncertain, the FTC may proffer a copy test for the record. Copy testing is the most probative form of extrinsic evidence.

A copy test that is prepared for litigation is conducted using procedures designed to minimize bias. Creation of a new copy test requires the crafting of a survey by an expert in consumer survey design, the actual implementation of the survey, and data entry and analysis to determine the results. The FTC staff has typically retained an expert trained in marketing, communications, or consumer behavior, to determine who should be included in the survey's population and to design the questionnaire that will be used to elicit those survey participants' responses. It is critical that the survey questionnaire be objective and unbiased to obtain probative data. Although a marketing expert designs the copy test, the attorney in the case also plays an important role in the process to ensure that the questions elicit information relevant to the proceeding. Thereafter, a consumer research provider is retained to put the copy test into "the field," typically at shopping malls, where consumers are solicited to determine their qualification and willingness to participate in the survey. The research company also provides data entry and statistical analysis.<sup>15</sup>

The total cost for such a survey varies. It is dependent on a number of factors, including how easy or difficult it is to find qualified consumers, how long the interview will take, how many consumers will view each ad, and how many ads need to be tested. In advertising cases involving commonly purchased consumer products, the cost of copy testing, excluding the cost of survey design, ranges from \$20,000 to \$50,000.

The specific design of the test must reflect the format and style of the particular advertisement, the media in which the advertising is run, and the product advertised. Each

advertisement, media, and accompanying alleged implied claim(s) typically present unique analytical issues that require various design techniques. The Commission and courts require that copy test evidence come from surveys that are methodologically sound, draw valid samples from the appropriate population, ask appropriate questions in ways that minimize bias, use any appropriate controls, and analyze results correctly.<sup>16</sup>

### **c. Expert Opinion**

Another form of extrinsic evidence sometimes used to prove that an ad communicates an implied claim to reasonable consumers is the opinion testimony of an expert witness based upon his or her facial analysis of the ad. In substance, this type of evidence is very similar to the facial analysis proffered by the litigating attorneys, but it is typically employed when the implied claim is not sufficiently clear. Here again, the experts used typically are academics in the fields of marketing, advertising, consumer behavior, or communications. The testimony they present is based upon their analysis of all the elements of the ad and must be supported by existing empirical research, generally recognized marketing principles, or other objective manifestations of professional expertise.<sup>17</sup> Such testimony has been relied upon, and upheld on appeal, in administrative and federal court cases.<sup>18</sup>

### **B. Falsity or Lack of Substantiation**

Once it has determined what claims have been conveyed to reasonable consumers, the Commission must then determine whether the claim is misleading. The Commission has relied upon two theories to make this determination: asserting that a claim is false and asserting that a claim is unsubstantiated. A claim is false where the scientific evidence demonstrates the falsity of the claim; it can also be false where it can be demonstrated that it is physically impossible for

the claimed results to be achieved. By contrast, a claim is unsubstantiated where the advertiser lacks a “reasonable basis” for asserting that the claim is true.<sup>19</sup> In practice, determining whether a claim is false or is unsubstantiated often requires the assistance of outside experts, as described below.

### **1. Expert Testimony**

As part of the investigation process, the Commission staff requests the advertiser’s substantiation for the claims at issue. Staff will then carefully review that substantiation, often with the help of outside experts. In many of the cases the Commission brings, the advertiser has little or no substantiation to support the challenged claims. In other cases, the advertiser produces documentation of research purporting to support its claims, but there are significant questions concerning the adequacy of the research. In such cases, expert testimony is often required to establish that the claims are unsubstantiated. Many of the FTC’s advertising substantiation cases involve health or appearance benefit claims for foods, drugs, or dietary supplements. The potential experts in these cases are Ph.D.’s or M.D.’s either in academia or private practice.

### **2. Proving A Claim Is Unsubstantiated**

The first step in building a substantiation case is to obtain all of the advertiser’s substantiation for that claim.<sup>20</sup> The expert must then evaluate the relevance<sup>21</sup> and scientific reliability of that material. The latter often involves an expert assessment of the adequacy of the design and conduct of a human clinical study,<sup>22</sup> of applicability of animal or *in vitro* studies to performance in humans,<sup>23</sup> the appropriateness or accuracy of statistical analyses,<sup>24</sup> and the consistency or fit of the proffered substantiation with the existing body of the relevant, well-

conducted scientific research.<sup>25</sup> Following this assessment, the expert forms an opinion regarding the adequacy of the advertiser's proffered substantiation.

Advertisers may retain their own expert witnesses to undertake a similar analysis. Not surprisingly, they often come to the opposite conclusion from the Commission's expert. Thus, the question of whether the advertiser's substantiation was adequate often becomes a question of fact as to the relevance and adequacy of the particular studies in the record. The Commission strives to use only the most qualified independent experts and to conduct a comprehensive review of all relevant substantiation.<sup>26</sup>

### **C. Materiality**

To prove that a claim is deceptive, the Commission staff must not only prove that the claim made was false or unsubstantiated, it must also show that the claim was "material." A claim is material if it presents information that is important to consumers and thus is likely to affect their choice of or conduct regarding a product.<sup>27</sup> FTC staff usually prove that a claim is material through the use of presumptions and documents from the advertiser or its advertising agency.

The Commission presumes that express claims, intentionally made implied claims, and claims significantly involving health, safety, or other areas with which reasonable consumers would be concerned (e.g., claims pertaining to the product's central characteristics, purpose efficacy, or cost) are material.<sup>28</sup> However, an advertiser may rebut this presumption by offering evidence that a claim made was not in fact important to consumers. If the advertiser rebuts the presumption of materiality, the Commission will consider all of the evidence in the record in determining whether the claim was material. The evidence considered includes the predicate

facts that triggered the presumption, for example, the fact that the advertiser was making a health claim.<sup>29</sup> The evidence considered also often includes internal company documents, such as survey evidence, marketing documents, and sales records.<sup>30</sup>

#### **D. Conclusion**

The record that the FTC staff will compile in a particular case contains evidence both as to ad interpretation and substantiation proffered in support of the challenged claims. Much of this information may come directly from the respondent's files. Other elements of the record, such as a copy test, may be developed by the staff in preparation for litigation. This effort to compile a thorough record both on ad meaning and substantiation has led to substantial success on the merits of the Commission's cases both at the trial stage and on appellate review.<sup>31</sup> Although developing such a record is time consuming and resource intensive, it is a critical aspect of fulfilling the agency's mission. The record developed in the investigation stage and in preparation for litigation establishes that a violation has occurred and informs the agency on the appropriate scope of remedies to cure the deception and prevent future misconduct. This approach has also been found to be consistent with the First Amendment commercial speech doctrine and its emphasis on providing consumers with access to truthful information so that they can make well-informed purchase decisions.

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1. *Novartis Corp.*, Dkt. No. 9279 (May 13, 1999), slip op. at 5, *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); *Kraft, Inc.*, 114 F.T.C. 40, 120 (1991), *aff'd*, 970 F.2d 311 (7<sup>th</sup> Cir. 1992), *cert. denied*, 507 U.S. 909 (1993); *Thompson Med. Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); Letter to Hon. John Dingell, Chairman, Committee on Energy and Commerce, from James C. Miller, Chairman, Federal Trade

Commission, 103 F.T.C. 174, 175-76, appended to *Cliffdale Assoc., Inc.*, (“Deception Statement”).

2. *Thompson Med. Co.*, 104 F.T.C. at 788.

3. Deception Statement, 103 F.T.C. at 176.

4. *Thompson Med. Co.*, 104 F.T.C. at 788-89; *see Kraft, Inc.*, 114 F.T.C. at 120.

5. *Stouffer Foods Corp.*, 118 F.T.C. 746, 798-99 (1994); *Kraft, Inc.*, 114 F.T.C. at 121-22; *Thompson Med. Co.*, 104 F.T.C. at 789-90.

6. Of course, any extrinsic evidence included in the record must be carefully considered.

7. *Kraft, Inc.*, 114 F.T.C. at 121; *Thompson Med. Co.*, 104 F.T.C. at 789; *see Removatron Int'l Corp.*, 111 F.T.C. 206, 292 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989).

8. *See FTC v. Febrè*, No. 94 C. 3625, 1996 WL 396117 at \*4 (N.D. Ill. July 3, 1996) (magistrate judge recommendation), *adopted by* 1996 WL 556957 (N.D. Ill. Sept. 27, 1996), *aff'd* 128 F.3d 530 (7<sup>th</sup> Cir. 1997); *FTC v. Gill*, 71 F. Supp. 2d 1030, 1043 (C.D. Cal. 1999). *See also FTC v. Arlington Press, Inc.*, 1999-1 Trade Cas. (CCH) ¶ 72,415 at 83,889 (C.D. Cal. 1999).

9. As the court succinctly stated in *FTC v. Sterling Drug*, 317 F. 2d 669, 674 (2d Cir. 1963), the Commission examines “the entire mosaic, rather than each tile separately.” *See also American Home Prods. Corp.*, 695 F.2d 681, 688 (3d Cir. 1982); *FTC v. US Sales Corp.*, 785 F. Supp. 737, 745 (N.D. Ill. 1992); Deception Statement, 103 F.T.C. at 179. A detailed example of how the Commission performs facial analysis of an ad is set out in the *Kraft* opinion. 114 F.T.C. 40, 123 *et seq.* (1991).

10. The merit of this practice was challenged in the *Kraft* case, where Kraft argued that the Commission’s use of facial analysis violated the First Amendment because it chilled some truthful commercial speech. However, that argument was rejected because the implied claims were “reasonably clear” from the face of the ad and because commercial speech is “generally considered less susceptible to the chilling effect of regulation than other, more traditionally recognized forms of speech, such as political discourse.” 970 F.2d at 321. The court of appeals in *Kraft* relied heavily on the Supreme Court’s opinion in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985). In that case, the Court upheld the finding that a lawyer’s advertising made a deceptive implied claim, explaining that “[w]hen the possibility of deception is as self-evident as it is in this case, we need not require the State to ‘conduct a survey of the . . . public before it [may] determine that the [advertisement] had a tendency to mislead.’” 471 U.S. at 652-53; *see* 970 F.2d at 321.

11. A copy test is a survey in which a sample of qualified consumers is shown an advertisement and then asked a series of questions about it to elicit their understanding of the claims made in the ad.

12. *Thompson Med. Co.*, 104 F.T.C. at 793-94; *Novartis Corp.*, slip op. at 8-9.
13. See *Novartis Corp.*, slip op. at 9; *Kraft, Inc.*, 114 F.T.C. 127 n.13; S. Bonamici, *The Use and Reliability of Survey Evidence in Deceptive Advertising Cases*, 62 Or. L. Rev. 561, 584-85 (1983) (forced exposure method is more probative because it focuses directly on the message of the ad as opposed to “day-after-recall” tests which are designed primarily to measure how memorable the message is) (citing *Bristol-Myers*, 85 F.T.C. 688, 718 (1975)).
14. See *Novartis Corp.*, slip op. at 9; *Kraft, Inc.*, 114 F.T.C. at 127 n.13; *American Home Prods. Corp.*, 98 F.T.C. 136, 416 (1981), *aff’d*, 695 F.2d 681 (3d Cir. 1982).
15. Many consumer research providers also have trained, competent research designers who also can provide questionnaire design work as well.
16. *Thompson Med. Co.*, 104 F.T.C. at 790; see *Kraft, Inc.*, 114 F.T.C. at 121. However, Commission law makes clear that “[p]erfection is not the prevailing standard for whether a copy test may be given any [evidentiary] weight.” *Stouffer Foods Corp.*, 118 F.T.C. at 807. Rather, the governing standard “is whether the evidence is reliable and probative.” *Id.* A copy test may be flawed or include one or more sources of potential error or bias and still be probative. *Id.* Thus, the Commission or the courts will evaluate the nature and seriousness of any such errors or biases to determine the weight it will give to copy test evidence. *Id.*; see *Selchow & Righter Co. v. Decipher, Inc.*, 598 F. Supp. 1489, 1502-03 (E.D. Va. 1984). The marketing literature also contains a number of articles that summarize many copy test design-related issues. See, e.g., Mazis, M.B., “Copy-Testing Issues In FTC Advertising Cases,” Marketing and Public Policy Conference Proceedings, 122-30 (1996).
17. See, e.g., *Thompson Med. Co.*, 104 F.T.C. at 790 n.11.
18. *Id.* at 799; *Kraft, Inc.*, 114 F.T.C. at 126 n.13; *FTC v. Brown & Williamson Tobacco Corp.*, 580 F. Supp. 981, 986 n.31 (D.D.C. 1983), *aff’d*, 778 F.2d 35 (D.C. Cir. 1985).
19. See, e.g., *Thompson Med. Co.*, 104 F.T.C. at 818-19.
20. It is not uncommon for advertisers under investigation or even in litigation to submit new studies or data as they locate or create it. This material is referred to as “post-claim substantiation” and cannot be considered as substantiation that the advertiser possessed and relied upon at the time the claim was disseminated. However, the Commission will consider it with regard to interpreting the adequacy of the substantiating materials or to developing the scope of the order issued against an advertiser for violating the substantiation doctrine. Substantiation Statement, 104 F.T.C. at 841.
21. See *FTC v. Pharmtech Research, Inc.*, 576 F. Supp. 294, 302 (D.D.C. 1983) (reliance on studies of vegetables not relevant substantiation for claims for dietary supplement); *Schering Corp.*, 118 F.T.C. at 1093 (Initial Decision) (studies of weight loss product given in conjunction with restricted calorie diet not relevant to substantiating ad claims that product causes weight loss).

without a diet).

22. See *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1092-93, 1097-98 (9<sup>th</sup> Cir. 1994) (clinical studies not placebo-controlled or double-blinded are not good scientific evidence); *SlimAmerica*, 77 F. Supp. 2d at 1274 (methodologically flawed studies are not valid scientific evidence); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1008 (N.D. Ill. 1998) (flawed placebo-controlled, double-blind study does not constitute valid scientific substantiation).

23. See *SlimAmerica*, 77 F. Supp. 2d at 1274 (animal and *in vitro* studies do not constitute good scientific evidence without proof that the effects would be the same in humans).

24. See *Sabal*, 32 F. Supp. 2d at 1008 (insufficient data reported to determine statistical significance); *Schering*, 118 F.T.C. at 1093 (re-analysis of data shows no statistical significance).

25. See *Pantron*, 33 F.3d at 1092, 1097 (consensus of scientific community, based on peer reviewed literature, negates efficacy evidence proffered by the advertiser).

26. See *Porter & Dietsch, Inc.*, 90 F.T.C. 770 (1977), *aff'd*, 605 F.2d 294 (7<sup>th</sup> Cir.), *cert. denied*, 445 U.S. 990 (1979); *Schering* (Initial Decision); *Pantron*; *Sabal*; *Pharmtech*.

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

28. See *id.*

29. *Novartis Corp.*, slip op. at 12.

30. See *id.* at 13-15; *Kraft, Inc.*, 114 F.T.C. at 135-38.

31. The Commission's analysis and evaluation of ad interpretation and substantiation issues is given deference on appeal under the so-called "substantial evidence" standard. Under this standard, the court must accept the Commission's findings so long as they are supported by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 454 (1986). Similarly, the standard for review the courts of appeals apply when reviewing a district court's assessment of copy test evidence is whether the trial judge's evaluation was clearly erroneous. See *Johnson & Johnson \* Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 301 (2d Cir. 1992).