

# LEGAL MEMORANDUM

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## Time to Reform FTC Advertising Regulation

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### Abstract

*The U.S. Federal Trade Commission, the principal federal consumer protection and competition watchdog, has a long history of vigorously combatting false and deceptive advertising under its statutory authorities, but recent efforts by the FTC to impose excessive “advertising substantiation” requirements on companies go far beyond what is needed to combat false advertising. Such actions threaten to discourage companies from providing useful information that consumers value and that improves the workings of the marketplace. They also are in tension with constitutional protection for commercial speech. The FTC should reform its advertising substantiation policy and allow businesses greater flexibility to tailor their advertising practices, which would further the interests of both consumers and businesses. It should also decline to seek “disgorgement” of allegedly “ill-gotten gains” in cases involving advertising substantiation.*

Advertising is a boon to the American economy.<sup>1</sup> By informing large numbers of consumers about the attributes of goods and services, it helps to create broad markets for those products, generating economies of scale that lower cost and prices.

Information embedded in advertising allows consumers to make better choices in the marketplace, benefiting ultimate purchasers and stimulating competition among producers. The market activity generated by advertising helps to create jobs, provides funding for the mass media, and facilitates the sponsorship of cultural and athletic events, yielding further economic welfare benefits. Advertising also stimulates innovation: Businesses have a greater incentive to improve products if they are able to communicate those improve-

### KEY POINTS

- The Supreme Court has held that government can restrict commercial speech (that is not misleading and does not concern illegal activity) no more than is necessary for the direct advancement of a legitimate governmental interest.
- The Federal Trade Commission recently has moved away from reasonableness-based, case-by-case advertising substantiation and has begun to impose extremely costly demands on makers of substantive advertising claims that could reduce the flow of useful commercial information, render advertising less effective, and harm consumers.
- Even worse, the commission has begun to invoke its authority under Section 13(b) of the FTC Act to seek disgorgement of firms’ assets in cases that do not involve clear fraud. This approach is in clear tension with the history and purpose of the statute and further burdens commercial speech to the detriment of consumer welfare and core First Amendment values.
- The FTC should keep commercial speech values in mind when deciding whether and how to challenge advertising.

This paper, in its entirety, can be found at <http://report.heritage.org/lm140>

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ments to prospective buyers. Consistent with these insights, studies show that countries with higher rates of advertising enjoy stronger economic growth.

In short, advertising in general promotes a strong market economy. False or deceptive advertising, however, undermines the market economy. It distorts competition among firms (harming companies that provide accurate information) and leads consumers who rely on falsehoods to make incorrect purchasing decisions.

The U.S. Federal Trade Commission (FTC), the principal federal consumer protection and competition watchdog, has a long history of vigorously combatting false and deceptive advertising under its statutory authorities,<sup>2</sup> but recent efforts by the FTC to impose excessive “advertising substantiation” requirements on companies go far beyond what is needed to combat false advertising. Such actions threaten to discourage companies from providing useful information that consumers value and that improves the workings of the marketplace.<sup>3</sup> They also are in tension with constitutional protection for commercial speech.

The FTC should reform its advertising substantiation policy and allow businesses greater flexibility to tailor their advertising practices, an action that would further the interests of both consumers and businesses. It should also decline to seek “disgorgement” of allegedly “ill-gotten gains” in cases involving advertising substantiation.

## Constitutional Protection for Commercial Speech

Government regulation of advertising must be viewed in light of the Constitution. In addition to protecting religious, political, and expressive speech, the First Amendment shields non-deceptive “commercial speech,” which encompasses most advertising and marketing.

The Supreme Court of the United States recognized almost 40 years ago that the free flow of commercial speech is “indispensable” to “intelligent and well informed” consumer decisions in the marketplace.<sup>4</sup> Shortly thereafter, the Court held that government could restrict commercial speech (if it is not misleading and does not concern illegal activity) no more than is necessary for the direct advancement of a legitimate governmental interest.<sup>5</sup>

This constitutional mandate means that government must avoid unnecessarily limiting the dissemination of advertising information in carrying out its enforcement mandates. Consistent with this insight, one FTC commissioner recently stressed that the FTC should not unduly burden the flow of legitimate, non-fraudulent advertising in advancing its statutory goals: In “protecting the marketplace and consumers from false commercial speech,” the FTC “must also help to foster an environment that provides consumers access to useful consumer information.”<sup>6</sup>

In short, the commission should keep in mind commercial speech values when deciding whether and how to challenge advertising.

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1. The following benefits of advertising are summarized in “The Value of Advertising,” available at <http://www.valueofadvertising.org/home.php>. For a concise overview of the economic benefits of advertising, see George Bittlingmayer, *Advertising*, in THE CONCISE ENCYCLOPEDIA OF ECONOMICS (2nd ed. 2008), available at <http://www.econlib.org/library/Enc/Advertising.html>. See also, e.g., *The FTC at 100: Testimony of Academic Experts: Hearing Before the Subcomm. on Commerce, Mfg., and Trade of the H. Comm. on Energy and Commerce*, 113th Cong. 2-3 (2014) (statement of J. Howard Beales III, Professor of Strategic Management and Public Policy, George Washington School of Business); Phillip Nelson, *Advertising as Information*, 82 J. POL. ECON. 729 (1984) (advertising stimulates investments in product quality); George J. Stigler, *The Economics of Information*, 64 J. POL. ECON. 213, 220 (1961) (advertising helps to eliminate ignorance).
  2. For a description of the advertising the FTC considers deceptive and a summary of the commission’s deceptive advertising enforcement program, see *Advertising FAQ’s: A Guide for Small Business*, available at <http://www.business.ftc.gov/documents/bus35-advertising-faqs-guide-small-business>.
  3. For example, economic studies have demonstrated that restrictions on advertising (including advertising that does not discuss prices) raise prices to consumers. See, e.g., *In re Polygram*, No. 9298, 2003 WL 21770765 at note 52 (FTC Final Order July 24, 2003) (discussing empirical studies that the FTC summarized).
  4. *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 765 (1976).
  5. *Cent. Hudson Gas & Electric Corp. v. Pub. Service Comm’n of New York*, 447 U.S. 557, 570 (1980).
  6. Maureen K. Ohlhausen, Commissioner, FTC, Back to the Future on 600 Pennsylvania Avenue, Remarks Before the ANA Advertising Law and Public Conference, at 3 (Apr. 23, 2014), available at [http://www.ftc.gov/system/files/documents/public\\_statements/300221/140423anaspeech.pdf](http://www.ftc.gov/system/files/documents/public_statements/300221/140423anaspeech.pdf).

## The FTC and False Advertising

FTC false advertising cases are based on the “deception” component of the commission’s general statutory authority to proscribe unfair or deceptive acts or practices.<sup>7</sup> In its 1983 “Policy Statement on Deception,” which remains officially in force, the commission defines “deception” as involving a “representation, omission or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer’s detriment.”<sup>8</sup> Thus, deception occurs only when business conduct causes tangible harm to consumers who acted reasonably and were misled.

Hard-core fraudulent advertising claims, which have been the subject of numerous FTC enforcement “sweeps” in recent decades,<sup>9</sup> clearly fall within this definition. Moreover, because there is no First Amendment right to engage in commercial deception,<sup>10</sup> FTC enforcement against hard-core fraud raises no constitutional issues.

But what about advertisements not involving hard-core fraud that claim that the products being touted yield specific benefits, such as lowering the risk of cancer? Unlike hard-core fraud cases, such advertisements typically involve disputes over scientific details, implicate established “legitimate” businesses with little risk of disappearing, and refer to products that have substantial value for other reasons (for example, food and other consumer products that engender substantial consumer

benefits without regard to whether particular advertised claims are accurate).<sup>11</sup> Those advertisements may greatly enhance social welfare—a fact that government should keep in mind in evaluating them.

The beneficial chain reaction sparked by Kellogg Cereals’ health-related claims illustrates this point. In 1984, Kellogg launched advertisements claiming that its All-Bran cereal may reduce the risk of certain cancers.<sup>12</sup> The science underlying those claims was uncertain: Kellogg’s claims were based principally on epidemiological studies rather than on human trials. The federal Food and Drug Administration (FDA) at first threatened to seize All-Bran as an unapproved new drug but backed away when the FTC and the National Cancer Institute defended Kellogg. An FTC staff report found that the Kellogg campaign inspired other cereal makers to advertise their fiber content and cancer risk-reduction properties.<sup>13</sup>

Other advertising claims about the relationship between diet and health began to proliferate, with similar impact on the marketplace. For example, claims about the relationship between diet and heart disease rose from under 2 percent to over 8 percent of all advertising between 1984 and 1989,<sup>14</sup> and consumption of fat and saturated fat (the primary dietary risk factors for heart disease) fell more rapidly after 1985.<sup>15</sup> In short, this new nutritional advertising promoted beneficial improvements in diet.

In the Kellogg matter, the FTC commendably declined to prohibit the novel advertisements

7. See 15 U.S.C. 45(a)(1). (The FTC’s “unfairness-related” enforcement initiatives fall outside the scope of this Legal Memorandum.) Additionally, 15 U.S.C. § 52(a) specifically authorizes the FTC to prohibit as deceptive the false advertising of foods, drugs, devices, cosmetics, and services.
8. FTC Policy Statement on Deception, Oct. 14, 1983, appended to Clifford Associates, Inc., 103 F.T.C. 110, 174 (1984), available at <http://www.ftc.gov/ftc-policy-statement-on-deception>.
9. See, e.g., *Financial Services and Products: The Role of the Federal Trade Commission in Protecting Consumers: Hearing Before the Subcomm. on Consumer Protection, Prod. Safety, and Ins. of the S. Comm. on Commerce, Sci., and Transp.*, 111th Cong. 37 (2010) (statement of Timothy J. Muris, George Mason University Foundation Professor of Law).
10. See, e.g., *Friedman v. Rogers*, 440 U.S. 1 (1979) (the states and the federal government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading).
11. See J. Howard Beales III & Timothy J. Muris, *Striking the Proper Balance: Redress Under Section 13(b) of the FTC Act*, 79 ANTITRUST L.J. 1, 35–36 (2013).
12. The following summary of the Kellogg matter is derived from J. Howard Beales, Timothy J. Muris & Robert Pitofsky, *In Defense of the Pfizer Factors in the Regulatory Revolution at the FTC*, in *A THIRTY-YEAR PERSPECTIVE ON COMPETITION AND CONSUMER PROTECTION* (James C. Cooper ed., 2013).
13. See Pauline Ippolito & Alan Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, FTC Staff Report (1989), available at <http://www.ftc.gov/reports/health-claims-advertising-labeling-study-cereal-market>.
14. See Pauline Ippolito & Janice Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising, 1977-1997*, FTC Staff Report at 69, Figure 5.2 (2002), available at <http://www.ftc.gov/reports/advertising-nutrition-health-evidence-food-advertising-1977-1997>.
15. See Pauline Ippolito & Alan Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990*, FTC Staff Report (1996), available at <http://www.ftc.gov/reports/information-advertising-policy-study-fat-cholesterol-consumption-united-states-1977-1990>.

despite the lack of clinical trials and convinced its sister agency, the FDA, to forbear intervening as well. The result was a public health gain as the success of the original advertisements spawned a virtuous competitive cycle that enhanced public knowledge of important food characteristics. In cereals, the risk of harm to the public if the health-related information had proven to be inaccurate was small, but the gain to the public in the event the information was accurate (multiple studies appear to support that conclusion)<sup>16</sup> was enormous.

As a general matter, this case-specific weighing of the harms and benefits of regulating advertising claims makes good policy sense and advances First Amendment values. In the process of promoting the flow of vital information to consumers, it avoids undermining constitutionally protected commercial speech by restricting it no more than is necessary.

### The FTC's Advertising Substantiation Program

The FTC has developed guidance regarding whether advertising product claims are sufficiently substantiated (as in Kellogg's) and therefore not deceptive. In its 1972 *Pfizer* decision,<sup>17</sup> the commission held that adequate substantiation meant an advertiser must have a "reasonable basis" for making objective claims. The FTC identified various factors that it would consider in deciding whether a "reasonable basis" was present, including (1) the type and specificity of the claim (e.g., safety, health, medical); (2) the type of product; (3) the possible consequences of a false claim (e.g., property damage, personal injury); (4) the degree of reliance by consumers on the claims; and (5) the type and acces-

sibility of evidence adequate to form a reasonable basis for particular claims.

Shortly thereafter, the FTC held that the failure to have a "reasonable basis" for objective claims was deceptive under Section 5 of the FTC Act.<sup>18</sup> Subsequently the FTC defined a "reasonable basis" as the possession of "competent and reliable scientific evidence," meaning "evidence based on the expertise of professionals in the relevant area, that has 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>19</sup>

In 1983, the commission released the "FTC Policy Statement Regarding Advertising Substantiation."<sup>20</sup> This statement of general guidance, which remains in force, enshrined a flexible standard for substantiation. If a commercial included an express or implied statement of the degree of support for a claim (say, "tests prove"), the FTC expected the advertiser to have that degree of support. The statement also indicated that the FTC would rely on case-specific cost-benefit analyses in deciding what constituted adequate substantiation and would continue to take into account the *Pfizer* factors.

In recent years, the FTC has dramatically increased the requirements that businesses must meet to pass advertising substantiation muster. For example, in 2010, in its *Iovate* (weight loss claims) and *Nestlé* (duration of diarrhea claims) orders,<sup>21</sup> the FTC provided that for certain claims:

[C]ompetent and reliable scientific evidence shall consist of at least two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product, conducted

16. See, e.g., Whole Grains Council, "What Are the Health Benefits?" (2013) (containing links to peer-reviewed academic studies setting forth anti-cancer and other health benefits associated with whole-grain high-fiber foods, including cereals), available at <http://wholegrainscouncil.org/whole-grains-101/what-are-the-health-benefits>.

17. *In re Pfizer Inc.*, 81 F.T.C. 23 (1972).

18. *In re Nat'l Dynamics Corp.*, 82 F.T.C. 488 (1973), modified, *In re Nat'l Dynamics Corp.*, 85 F.T.C. 391 (1985).

19. *In re Novartis Corp.*, 127 F.T.C. 580, 725 (1999).

20. FTC Policy Statement Regarding Advertising Substantiation, appended to *Thompson Med. Co.*, 104 F.T.C. 648, 839-40 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

21. *FTC v. Iovate Health Services USA, Inc.*, No. 10-CV-587, slip op. at 7 (W.D.N.Y. July 2010) (Stipulated Final Judgment), available at <http://www.ftc.gov/sites/default/files/documents/cases/2010/07/100729iovatestip.pdf>; *In re Nestlé HealthCare Nutrition, Inc.*, No. 092-3087, Agreement Containing Consent Order at 4 (July 14, 2010), available at <http://www.ftc.gov/sites/default/files/documents/cases/2010/07/100714nestleorder.pdf>.

by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and scientific evidence, are sufficient to substantiate that the representation is true.

*Nestlé* also required prior FDA approval of certain claims. The FTC has mandated two randomized controlled tests (RCTs) in other cases, such as *Dannon*,<sup>22</sup> and has made clear in senior staff statements that it intends to continue to pursue an aggressive substantiation policy, which emphasizes clinical trials.<sup>23</sup> Such broad “fencing in” relief (imposition of behavioral requirements that are more extensive than required to avoid future violations) goes well beyond prior FTC practice and may be aimed at “encouraging” other firms in similar industries to adopt costly new testing.<sup>24</sup>

The FTC also has begun to require FDA pre-approval of future claims in various consent decrees.<sup>25</sup> This is a troublesome development, particularly in light of research suggesting that the FDA pays insufficient attention to the benefits of new drugs.<sup>26</sup>

This new set of requirements (which moves in the direction of FDA-style drug regulation) is extremely onerous. Kellogg’s socially beneficial advertisements of the benefits of All-Bran, which were not backed by human clinical studies, would not have satisfied these requirements. Moreover, the mandate that different researchers must carry out human clinical studies imposes substantial new costs.

All told, these new burdens may deter firms from investing in new health-related product improvements, in which event consumers who are denied new and beneficial products (as well as useful information about the attributes of current products) will be the losers. Competition will also suffer as businesses shy away from informational advertising that (as in the Kellogg case) rewards the highest quality current products and encourages firms to compete on the basis of quality. Furthermore, the broad scope of these requirements is in tension with the constitutional prohibition on restricting commercial speech no more than is necessary to satisfy legitimate statutory purposes.

The FTC went even further in limiting commercial speech in its 2013 *POM Wonderful LLC* decision,<sup>27</sup> finding that the POM Wonderful company made 36 deceptive claims in advertisements that its juice products could prevent or reduce the risk of various diseases, such as heart disease and prostate cancer. This decision was based on individual commissioners’ views that claims appeared to be deceptive, not on scientific evidence. Moreover, the commission’s decision had three major problems.<sup>28</sup>

*First*, it found it sufficient for a violation that a “significant minority” of consumers was deceived, despite the fact that studies show that virtually any communication deceives a certain percentage of consumers. This moves away from the emphasis in the “Policy Statement on Deception” on the perspective of the “average listener” or the “typical buyer.”

*Second*, the FTC relied excessively on the need for randomly controlled clinical trials, despite the

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22. *In re Dannon Company, Inc.*, No. 082-3158, Agreement Containing Consent Order at 4 (Dec. 15, 2010), available at <http://www.ftc.gov/sites/default/files/documents/cases/2010/12/101215dannonagree.pdf>.

23. See, e.g., Jessica Rich, Director, Bureau of Competition, FTC, The FTC’s Consumer Protection Program: Current Priorities in Advertising and Privacy, Address at the Kelley, Drye & Warren Advertising Summit (June 12, 2014), available at [http://www.ftc.gov/system/files/documents/public\\_statements/411821/140612kdwspeech.pdf](http://www.ftc.gov/system/files/documents/public_statements/411821/140612kdwspeech.pdf).

24. See Randal Shaheen & Amy Ralph Mudge, *Has the FTC Changed the Game on Advertising Substantiation?*, 25 ABA ANTITRUST SOURCE 65, 67-68 (Fall 2010) (advertisers should assume that new requirements apply irrespective of whether they are subject to a consent order), available at [http://www.americanbar.org/content/dam/aba/publishing/antitrust\\_source/Fall10\\_ShaheenC.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/Fall10_ShaheenC.authcheckdam.pdf).

25. See *id.* at 67.

26. See, e.g., Kip Viscusi, *Regulatory Reform and Liability for Pharmaceuticals and Medical Devices*, in *ADVANCING MEDICAL INNOVATION: HEALTH, SAFETY, AND THE ROLE OF GOVERNMENT IN THE 21ST CENTURY* 79, 90 (1996) (FDA approval process establishes excessive safety incentives and inadequately takes into account harm to current patients).

27. *In re POM Wonderful, LLC*, Docket No. 9344, available at [http://www.ftc.gov/system/files/documents/public\\_statements/568951/130116pomopinion.pdf](http://www.ftc.gov/system/files/documents/public_statements/568951/130116pomopinion.pdf). POM Wonderful has appealed the FTC’s decision in this matter to the U.S. Court of Appeals for the District of Columbia Circuit.

28. See Brief of Consumer Healthcare Products Association and Council for Responsible Nutrition in Support of Petitioners’ Request for Reversal, *POM Wonderful, LLC v. Fed. Trade Comm’n*, No. 13-1060, (D.C. Cir. Aug. 21, 2013), available at [http://www.crnusa.org/pdfs/r\\_8475.pdf](http://www.crnusa.org/pdfs/r_8475.pdf).

fact that they are excessively costly, unnecessary, and impractical in the case of food advertisements (double-blind trials including consumers who do not consume a type of food product could take decades). In so doing, the FTC also ignored the fact that the FDA has approved health claims for food additives based on epidemiology and basic science without requiring clinical trials.

*Third*, the FTC's requirement for a second clinical trial is likely to suppress truthful and useful claims, thereby harming consumers. A second clinical trial is very costly and may well lead to the incorrect rejection of truthful claims. It may also cause advertisers to focus instead on intangible product features, such as "image" or packaging, that are less directly useful to consumers. This is the polar opposite of the Kellogg case, which generated useful competition based on health-related factors.

Major advertisers may be expected to take note of *POM Wonderful's* restrictive implications and adjust their advertising strategies accordingly. Unless the *POM Wonderful* decision is overturned on appeal, it threatens to drive useful commercial speech out of the marketplace. Such a result would harm consumer welfare and undermine constitutional protection for commercial speech.

### **The FTC's New Disgorgement Policy Applied to Advertising Substantiation**

The FTC also has pursued monetary relief against parties that it believes have inadequately substantiated their claims. It has done this under Section 13(b) of the FTC Act,<sup>29</sup> which authorizes the commission "in proper cases" to seek a permanent injunction in federal district court. Although "the legislative history supports a strong argument that Congress never intended to grant the FTC broad authority to seek consumer redress under Section 13(b),"<sup>30</sup> numerous federal courts since 1982 have

invoked that statute's language to freeze fraudsters' assets and authorize the payment of compensation to defrauded consumers.<sup>31</sup> In other words, the term "permanent injunction" has been used by the FTC as leverage to extract monies from businesses.

Until recently, the FTC invoked Section 13(b) only to pursue firms that had engaged in clear fraud, such as the sale of worthless products. Beginning in 2011, however, the commission entered into a large number of consent decrees in which it obtained the disgorgement of business assets and payments to consumers in cases that simply alleged inadequate substantiation for claims in national advertising campaigns. The settlement amounts have been significant; for example, the FTC obtained \$40 million in the *Skechers* settlement, involving allegedly unsubstantiated health benefit claims in advertisements for "muscle toning" shoes.<sup>32</sup>

A recent legal analysis by former FTC Chairman Timothy Muris and former FTC Bureau of Consumer Protection Director Howard Beales concluded that advertising substantiation matters (which typically involve legitimate products and services valued by consumers) do not constitute "proper cases" (cases involving clearly fraudulent conduct) to which Section 13(b) was meant to apply.<sup>33</sup> As the authors point out, "because such cases often depend on complicated scientific evidence, the risk of mistakenly prohibiting truthful claims is relatively high."<sup>34</sup>

Furthermore, "[t]he knowledge that the FTC might seek consumer redress in such circumstances [cases not involving clear fraud] could chill...companies from providing consumers with information that they would want to have about the products they are using."<sup>35</sup> This sort of chill not only harms consumer welfare, but also ignores the Supreme Court's admonition that "the consumer's concern for the free flow of commercial speech may often be keener than his concern for urgent political dialogue."<sup>36</sup>

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29. 15 U.S.C. § 53(b).

30. Beales & Muris, *supra* note 11, at 26.

31. See *id.* at 23–28.

32. Press Release, Fed. Trade Comm'n, *Skechers Will Pay \$40 Million to Settle FTC Charges That It Deceived Consumers with Ads for "Toning Shoes"* (May 16, 2012), available at <http://www.ftc.gov/news-events/press-releases/2012/05/skechers-will-pay-40-million-settle-ftc-charges-it-deceived>.

33. See Beales & Muris, *supra* note 11, at 33–43.

34. *Id.* at 37–38.

35. *Id.* at 39.

36. *Bates v. State Bar of Arizona*, 433 U.S. 350, 364 (1977).

## What Should Be Done

In sum, the FTC recently has moved away from a reasonableness-based, case-by-case advertising substantiation inquiry, which accorded businesses substantial leeway to advertise beneficial characteristics of their products. Instead, it has abruptly begun to impose extremely costly and impractical demands on makers of substantive advertising claims that threaten to reduce the flow of useful commercial information, render advertising less effective, and harm consumers.

Even worse, the commission has begun to invoke its authority under Section 13(b) of the FTC Act to seek disgorgement of firms' assets in cases that do not involve clear fraud. This approach, which is in clear tension with the history and purpose of the statute, further burdens commercial speech to the detriment of consumer welfare and core First Amendment values.

In order to rectify these problems, the FTC should seriously consider two reforms. Specifically, the commission should:

- **Issue** a revised "FTC Policy Statement Regarding Advertising Substantiation." The revised statement, which would apply to cases other than hard-core fraud, should state that the FTC:
  1. Will seek to restrict commercial speech to the smallest extent possible, consistent with fraud prevention;
  2. Will apply strict cost-benefit analysis in investigating advertising claims and framing remedies in advertising substantiation cases;
  3. Will apply a reasonableness standard in such cases, consistent with the general guidance found in *Pfizer* and the 1983 policy statement;

4. Will not require clinical studies be conducted in order to substantiate advertising claims;
5. Will not require that the FDA or any other agency be involved in approving or reviewing advertising claims; and
6. Will avoid excessive "fencing end" relief that extends well beyond the ambit of the alleged harm associated with statements that the FTC deems misleading.

- **Issue** guidance clarifying that it will seek equitable remedies under Section 13(b) of the FTC Act only in cases of clear, unambiguous fraud and will not classify disputes over advertising substantiation as involving clear fraud. This guidance should be issued in a formal manner, perhaps in the form of a "Policy Statement on Monetary Equitable Remedies in Consumer Protection Cases."

Taken together, these reforms would restore the FTC's focus to truly fraudulent conduct. This would allow greater leeway for legitimate businesses to communicate effectively through advertising, thereby promoting consumer welfare and restoring proper respect for First Amendment commercial speech.

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