FROM DOG FOOD TO PRESCRIPTION DRUG ADVERTISING: LITIGATING FALSE SCIENTIFIC ESTABLISHMENT CLAIMS UNDER THE LANHAM ACT

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I. INTRODUCTION

Advertising is an ancient practice, at least two thousand years old.[1] But *comparative* advertising is a truly modern phenomenon, just twenty years old.[2] It is also a uniquely American activity. While comparative advertising is disdained in most other countries,[3] it is commonplace here.[4]

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[1] Advertising in the modern sense dates from Rome and Pompeii:

> It is in the records of Rome . . . and Pompeii that we first find advertising which comes within the modern meaning of the term. This advertising consisted of persuasive announcements painted on walls in black or red. Examples of it uncovered . . . in the ruins of Pompeii indicate that the commercial world was beginning to develop advertising sense two thousand years ago, and that *written* advertising came soon after the spread of literacy in ancient Rome, only to disappear with the decline in ability to read that followed and lasted through centuries of the Dark Ages.

FRANK PRESBREY, THE HISTORY AND DEVELOPMENT OF ADVERTISING 6-7 (1968) (emphasis in original).

[2] In the early 1970s, the Federal Trade Commission (FTC) encouraged the television networks to broadcast comparative advertisements. Before the FTC acted, advertisers shunned comparative advertising as "unethical." *See, e.g., Comparative Advertising is not for the Faint of Heart*, 24 EXECUTIVE, Dec. 1982, at 49, 49 (until the FTC acted, comparative advertising was "frowned on by professional codes, media guidelines, and government restrictions"); Robert Posch, Jr., *Comparative Advertising Yesterday and Today*, DIRECT MARKETING, May 1982, at 106, 106 (Until the last 10 years, "self-imposed media and professional regulations discouraged comparative advertising"); Stephen W. Brown & Donald W. Jackson, Jr., *The Current Status of Comparative Advertising*, ARIZ. BUS., Feb. 1979, at 3, 3-4 ("[T]he practice of using comparative [advertising] is relatively new." Prior to the 1970s, advertisers stayed away from comparative advertising "due to an unwritten code of honor within the advertising industry."); Thomas E. Barry & Roger L. Tremblay, *Comparative Advertising: Perspectives And Issues*, 4:4 J. OF ADVERTISING 15, 16 (1975) (Until the FTC acted, comparative advertising represented a technique avoided for many years).

[3] Comparative advertising remains illegal in many countries. *See* J.J. Boddewyn, *The One and Many Worlds of Advertising: Regulatory Obstacles and Opportunities*, 7:1 INT'L

Comparative advertising has proven to be a powerful technique.[5] Practically overnight, it can transform an obscure product into a market leader.[6] Thus, advertisers have recently employed powerful comparative advertising campaigns to promote all types of goods and services, from sophisticated personal computers[7] to simple hamburgers.[8] Even hospitals[9] and state

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J. OF ADVERTISING 11 (1988). In general, common law countries tend to tolerate comparative advertising except in "extreme cases of bad faith," whereas "civil law nations do not tolerate" comparative advertising. *See* J.J. Boddewyn, *Nations Apply Different Laws to Comparison Ads*, MARKETING NEWS, Oct. 6, 1978, at 3, 3.

[4] *See, e.g.*, *Comparative Advertising: Red in Tooth and Claw*, THE ECONOMIST, May 18, 1991, at 79, 79 (comparative advertising "grows ever more popular — and pointed — in America"); Darrel D. Muehling & Norman Kangun, *The Multi-Dimensionality of Comparative Advertising: Implications for the Federal Trade Commission*, J. OF PUB. POL'Y AND MARKETING 112, 112 (1985) ("Comparative advertising is becoming more common and is increasingly being used by companies in diverse industries."); Patricia Winters & Wayne Wally, *Coke Seeks Tough TV Ad Watchdog*, ADVERTISING AGE, Oct. 8, 1990, at 1, 1 (noting a "dramatic rise" in the use of comparative advertising); Meryl Freeman, *Comparative Cautions*, MARKETING AND MEDIA DECISIONS, Sept. 1987, at 82, 82 ("Over one-third of today's advertising is comparative.").

[5] *See, e.g.*, William L. Wilkie & Paul W. Farris, *Comparison Advertising: Problems and Potential*, J. OF MARKETING, Oct. 1975, at 7, 15 (comparative advertising represents "a powerful tool for the marketer"); Darrel D. Muehling et al., *The Impact of Comparative Advertising on Levels of Message Involvement*, 19:4 J. OF ADVERTISING 41 (1990) (finding that consumers pay greater attention to comparative advertising and hence it is more effective); Ronald L. Earl & William M. Pride, *Do Disclosure Attempts Influence Claim Believability and Perceived Advertiser Credibility?*, 12:1 J. OF THE ACAD. OF MARKETING SCI. 23, 24 (1984) (comparative advertising may increase consumer confidence in product claims); Aimee L. Morner, *It Pays to Knock Your Competitor*, FORTUNE, Feb. 13, 1978, at 104, 105 ("Comparative advertising was slow to catch on . . . . [b]ut it sells the goods"); Cornelia Pechmann & David W. Stewart, *The Effects of Comparative Advertising on Attention, Memory, and Purchase Intentions*, 17:2 J. OF CONSUMER RES., Sept. 1990, at 180, 188 (comparative advertising can increase purchase intentions for low-marketshare brands); *Some Comparative Ads Work, O&M Concedes*, ADVERTISING AGE, Nov. 3, 1980, at 6, 6 (comparative advertising can be a potent "short-term tactical weapon"); Herschell G. Lewis, *The Art of Comparative Copy*, CATALOG AGE, Apr. 1990, at 103, 103 (comparative advertising is one of the strongest devices); Darrel D. Muehling, et al., *Comparative Advertising: Views from Advertisers, Agencies, Media, and Policy Makers*, 29:5 J. OF ADVERTISING RES., Oct./Nov. 1989, at 38, 47 (comparative advertising constitutes "a very persuasive technique"); M. Carole Macklin & Crofford J. Macklin, Jr., *Refuting a Competitor's Advertising Claim*, 8 J. OF BUS. STRATEGY, Summer 1987, at 71, 71 (comparative advertisements become lethal weapons when used by competitors); Cornelia Droge & Rene Y. Darmon, *Associative Positioning Strategies Through Comparative Advertising: Attribute Versus Overall Similarity Approaches*, 24 J. OF MARKETING RES., Nov. 1987, at 377, 385 (comparative advertising shown empirically to promote better overall brand positioning); Z.S. Demirdjian, *Sales Effectiveness of Comparative Advertising: An Experimental Field Investigation*, 10:3 J. OF CONSUMER RES. 362, 362 (1983) (comparative advertising, with objective information concerning the products, "outweighs its noncomparative counterpart in sales effectiveness").

[6] Leslie Wines, *Name Calling*, MADISON AVENUE, Apr. 1985, at 54, 54.

[7] *See* Chris Lewis, *The Young Man and the PC*, DIRECTOR, Apr. 1991, at 63, 64

governments[10] have resorted to it.

While comparative advertising may take many forms,[11] one type stands out as the most effective. This type of advertising not only claims that a product is better than competing products, but cites a scientific study or test to "establish" the claim. Advertisers have found that "scientific establishment claims" — claims of scientifically-proven superiority — are quite effective.[12] This is not surprising in view of the strong hold of science in our society. To the modern consumer, information labeled as "scientifically proven" often assumes a posture of "mystic infallibility."[13]

Of those industries initially resorting to comparative advertising, the pharmaceutical industry has been the most active.[14] Comparative drug advertising, however, implicates unique social

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(discussing Dell Computer's use of comparative advertising to compete with more established marketers of PCs).

8 Burger King's comparative advertising campaign in the early 1980s, which launched "the Burger Battles," was spectacularly effective; it caused Burger King to post "the largest monthly gain in awareness of any advertiser," while McDonald's "suffered the largest decline recorded to date by any advertiser." Joseph Winski, *Burger King Gets Awareness Boost*, ADVERTISING AGE, Nov. 29, 1982, at 3, 3.

9 One hospital advertised its mortality rates from bypass surgery, but commentators disagree about the future of comparative advertising in this very sensitive domain. *See* Linda J. Perry & Kari Super Palm, *Hospitals Unlikely to Tout Mortality Data*, MODERN HEALTHCARE, Dec. 4, 1987, at 68, 68; Karl E. Super, *Nation's Hospitals Likely to Adopt Market Segmentation Techniques*, MODERN HEALTHCARE, Aug. 15, 1986, at 88, 90 (predicting that hospitals "may use comparative advertising to differentiate themselves" in terms of quality of care); Linda Little, *Medicine's Uneasy Bid for Business*, MADISON AVENUE, May 1985, at 90, 98 (hospitals may someday use "direct, point-by-point comparative advertising").

10 *See* Kevin T. Higgins, *True Marketing Absent in Economic-Development Efforts*, MARKETING NEWS, Oct. 11, 1985, at 1, 1 (state economic development authorities have engaged in comparative advertising to attract industry).

11 *See* Edmond R. Rosenthal, *Comparative Ad, Weapon or Fad?*, MARKETING TIMES, Sept./Oct. 1976, at 10, 10.

12 *See, e.g.*, Jerry B. Gotlieb & Dan Sarel, *Comparative Advertising Effectiveness: The Role of Involvement and Source Credibility*, 20:1 J. OF ADVERTISING 38, 44 (1991) (effectiveness of comparative advertising increases when "a source of higher credibility [*e.g.*, science] is included in the advertisement"); Earl & Pride, *supra* note 5, at 24 (performance test results significantly increase the effectiveness of comparative advertising); *Some Comparative Ads Work, O&M Concedes*, *supra* note 5, at 6 (credibility of comparative advertising is enhanced by "visual demonstrations of product superiority"); *cf.* Mary Ann Stutts, *Comparative Advertising and Counterargument*, 10:3 J. OF ACAD. OF MARKETING SCI. 302, 302 (1982) (comparative advertising effectiveness occurs when "readers of the advertisement must in some way accept the message that is presented in the advertisement"); David A. Aaker & Donald Norris, *Characteristics of TV Commercials Perceived as Informative*, J. OF ADVERTISING RES., Apr./May 1982, at 61, 70 (noting that "people listen to ads to obtain information," and "informative commercials are perceived to be convincing, effective, and interesting").

13 United States v. Addison, 498 F.2d 741, 744 (D.C. Cir. 1974).

14 For a discussion of the results of a 1975 study, *see* Stephen W. Brown & Don-

and competitive concerns. False comparative claims concerning medicines can affect the health of millions. In most instances, consumers, and even physicians, would be unable to meaningfully evaluate the claims and sales of the competing products could be dramatically affected. Hence, the stakes involved in these advertising campaigns — both the incentives to make a false scientific establishment claim or litigate to stop one — can be enormous.

The Lanham Act provides a private right of action for unfair competition based on false scientific establishment claims.[15] Courts have recently addressed Lanham Act challenges to scientific establishment claims in advertising for products literally ranging from dog food[16] to prescription drugs.[17] Cases involving comparative drug advertising, however, stand in a class of their own for several reasons. They can have profound implications for public health and drug development. Consumers and physicians are particularly unable to evaluate the merits of these claims. Moreover, they intersect with an extensive body of federal regulations governing drug advertising.

This article explores the public policy considerations and legal standards in a Lanham Act litigation involving comparative drug advertising based on scientific claims. To fully comprehend these public policy considerations and legal standards, it is essential to consider the broader social and regulatory context in which they operate.

Part II first examines the social utility of comparative drug advertising and then addresses how comparative drug advertising is directly regulated by the federal government, particularly the Federal Food and Drug Administration (FDA) and the Federal Trade Commission (FTC). It shows that, while truthful comparative drug advertising can benefit consumers in many ways, false comparative advertising may cause serious harm. The FDA and the FTC have recognized, therefore, that the law should seek to discourage false advertising, but not in an overly restrictive way that might simultaneously chill truthful comparative adver-

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ald W. Jackson, *Comparative Television Advertising: Examining its Nature and Frequency*, 6:4 J. OF ADVERTISING 15 (1977).

15 *See infra* note 102 and accompanying text.

16 Alpo Petfoods, Inc. v. Ralston Purina Co., 720 F. Supp. 194 (D.D.C. 1989), *aff'd in part, rev'd in part*, 913 F.2d 958 (D.C. Cir. 1990), *modified*, 1991 WL 25793 (D.D.C. Feb. 8, 1991).

17 E.R. Squibb & Sons, Inc. v. Stuart Pharmaceuticals, No. 90-1178, 1990 WL 159909 (D.N.J. Oct. 16, 1990).

tising. Because the Lanham Act indirectly regulates comparative advertising through private civil actions, courts must likewise seek to strike a suitable balance in deciding Lanham Act claims based on comparative drug advertising.

Part III shows how the Lanham Act has recently evolved into an effective remedy for false comparative advertising and the elements of a basic claim. Previously, ancient legal principles limited the effectiveness of private false advertising claims. With recent statutory changes, however, the Lanham Act has now matured into a very potent device for regulating false advertising.

Finally, Part IV addresses the legal standards governing scientific establishment claims under the Lanham Act. It explores the common fact patterns in these cases and the legal and scientific issues involved in their resolution. In conclusion, it argues that government agencies and courts should follow the same approach in regulating scientific establishment claims in comparative drug advertising.

II. COMPARATIVE DRUG ADVERTISING: PUBLIC POLICY AND PUBLIC REGULATION

A. The Social Utility of Comparative Drug Advertising

Companies advertise to sell their products. Advertising, however, is not simply a necessary evil of a market-based system. Economists, advertisers, regulators and businessmen recognize that honest and accurate comparative advertising can benefit consumers.[18]

1. Consumer Education

Truthful comparative advertising educates the consumer. The FTC has found that this type of advertising may assist consumers in making informed purchases by providing them with important product information.[19] When consumers are unin-

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[18] *See Study Cites Value of Comparative Ads But Warns Effect Hinges on Honesty*, BROADCASTING, Aug. 29, 1977, at 52, 52 (study by the National Advertising Review Board of the Better Business Bureaus).

[19] Posch, *supra* note 2, at 106. The FTC Policy Statement on comparative advertising notes:

> The Commission has supported the use of brand comparisons where the bases of comparison are clearly identified. Comparative advertising, when truthful and non-deceptive, is a source of important information to consumers and assists them in making rational purchase decisions.

Id. (citations omitted). *See generally* Stanley I. Tannenbaum & Andrew G. Kershaw,

formed or misinformed about a product, the demand for that product will not reflect its true utility.[20] Comparative advertising may even help transform the modern consumer. One commentator has suggested that the very phenomenon of comparative advertising motivates the consumer to compare before buying.[21] In other words, it induces the consumer to think.

In recent comments on proposed FDA regulations to govern nutritional claims in food advertising, the FTC clearly indicated that the communication of truthful information to consumers would significantly contribute to the public welfare.[22] The FTC noted that truthful information can educate the public about important health issues:

> [A]dvertising has played an important role in informing consumers about the relationship between diet and health. In the early 1970's, for example, food manufacturers were advising consumers to reduce cholesterol levels by substituting polyunsaturated fats for some saturated fats. Similarly, other advertisers promoted egg substitutes as a way to help meet the American Heart Association's then-recommended levels of dietary cholesterol intake.[23]

Thus, truthful advertising comprises a powerful method of disseminating information that may enable consumers to improve their health.[24] Drug advertising directed to the public could, for example, educate consumers about the health consequences of particular

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For and Against Comparative Advertising, ADVERTISING AGE, July 5, 1976, at 25, 25 (comparative advertising constitutes industry's own kind of consumerism); Muehling & Kangun, *supra* note 4, at 112 (FTC support for comparative advertising is based on view that it "provides consumers with more factual product information on which to make intelligent purchase decisions"); Robert R. Harmon et al., *The Information Content of Comparative Magazine Advertisements*, 12:4 J. OF ADVERTISING 10, 10 (1983) (comparative advertisements "have more information than noncomparative advertisements"); J.J. Boddewyn & Katherine Marton, *Comparison Advertising and Consumers*, 7:4 J. OF CONTEMP. BUS. 135, 136 (1979) (consumer associations generally approve the use of comparative advertising).

20 *See* Howard Beales, *Benefits and Costs of Label Information Programs*, *in* BANBLURY REPORT 6: PRODUCT LABELING AND HEALTH RISKS (Louis A. Morris et al., eds., 1980); Ralph K. Winter, *Advertising and Legal Theory*, in ISSUES IN ADVERTISING: THE ECONOMICS OF PERSUASION 15, 18 (David G. Tuerck ed., 1978).

21 Tannenbaum & Kershaw, *supra* note 19, at 25.

22 *Comments of the Bureaus of Competition, Consumer Protection and Economics of the Federal Trade Commission Submitted to the FDA in Response to a Request for Comments on its Proposal to Amend the Rules Governing Health Messages on Food Labels and Labeling*, at 1 (May 2, 1989) [hereinafter *Comments Regarding Health Messages*.] For the proposed amendments, *see* 52 Fed. Reg. 28843 (1987).

23 *Comments Regarding Health Messages*, *supra* note 22, at 5-6 (footnotes omitted).

24 *Id.* at 10.

illnesses and the drugs used to treat them.[25]

2. Product Improvement

Comparative advertising motivates producers to enhance the quality of their products.[26] Economists have stressed that comparative advertisements may induce competitors to improve the quality of their products,[27] and empirical data support this proposition.[28]

The FTC has long recognized that truthful comparative advertising may provide manufacturers with incentives to improve their products. Thus, for example, the FTC recently concluded that allowing manufacturers greater latitude to emphasize their products' health benefits will typically increase the demand for those products.[29] The increased consumer demand should then induce manufacturers to produce more desirable products.

3. Lower Prices and More Choices

Comparative price advertising encourages vigorous price competition.[30] Courts have long maintained that comparative price advertising may benefit consumers in this manner,[31] and substantial empirical data show that comparative price advertising lowers prices.[32]

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25 James D. Dickinson, *Ads to Consumers on the Hot Seat*, DRUG TOPICS, June 21, 1982, at 63, 67.

26 *See* Al McClain, *When it Comes to Commercials, Iacocca Wins Out*, ADVERTISING AGE, June 6, 1983, at M-30, M-32 (advertising executives feel that comparative advertising is advantageous because "[i]t motivates the advertiser to improve his products or suffer a bad comparison").

27 Michael B. Mazis et al., *A Framework for Evaluating Consumer Information Regulation*, 45 J. OF MARKETING 11, 11-12 (Winter 1981).

28 *See* J. Howard Beales III, *What State Regulators Should Learn From FTC Experience in Regulating Advertising*, 10 J. PUB. POL'Y & MARKETING 101, 102 (1991). For other empirical studies, *see* Pauline M. Ippolito & Alan D. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market* (FTC Bureau of Econ. 1989); Stutts, *supra* note 12, at 302.

29 *Comments Regarding Health Messages*, *supra* note 22, at 10.

30 O. Randolph Rollins, *Comparative Price Advertising*, 33 BUS. LAW. 1771, 1774 (Apr. 1978).

31 *See, e.g.*, Smith v. Chanel, Inc., 402 F.2d 562, 567-68 (9th Cir. 1968) ("To prohibit use of a competitor's trademark for the sole purpose of identifying the competitor's product would bar effective communication of claims of equivalence. . . . [T]he public interest would not be served by a rule of law which would preclude sellers . . . from advising consumers of knowledge that an identical product was being offered at one-third the price.").

32 *See* John R. Schroeter, *Advertising and Competition in Routine Legal Service Markets: An Empirical Investigation*, 36 J. OF INDUS. ECON. 49, 59 (1987); Beales, *supra* note 28, at 102.

Experience in the over-the-counter (OTC) drug market has proven the value of comparative price advertising. In one of the earliest and most notorious comparative price advertising campaigns, advertisements for Datril caused Johnson & Johnson to substantially reduce its price for Tylenol.[33]

Comparative advertising can also increase competition by lowering barriers to market entry.[34] Comparative advertising is particularly effective in reducing market barriers when a few manufacturers control the market by marching in lockstep.[35] It may be that, for this reason, market leaders have historically opposed comparative advertising.[36]

Comparative advertising may benefit all consumers even though a majority of them may not directly use the information conveyed by the advertising. As one commentator recently observed:

> All consumers benefit from advertising, even though a minority of consumers actively searches [sic] for products with lower prices or particular attributes. *Competition among manufacturers*

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[33] *See Tylenol Exec Speaks Out on Datril Price Ad*, ADVERTISING AGE, Mar. 29, 1976, at 1, 115 ("The Datril situation is apparently what the FTC had in mind when it encouraged [comparative advertising] in 1971. . . . [T]he subsequent price cut for Tylenol [proved] a definite advantage for the consumer.").

[34] *See Comparative Advertising: Red in Tooth and Claw*, *supra* note 4, at 79 (comparative advertising is an effective way for new brands to break into markets occupied by entrenched rivals); Easwar S. Iyer, *The Influence of Verbal Content and Relative Newness on the Effectiveness of Comparative Advertising*, 17:3 J. OF ADVERTISING 15, 20 (1988) (comparative advertising is effective for "new brand introductions" because it "facilitates the creation of a clear product position"); William J. Byer & Ernest F. Cooke, *Comparative Advertising's Dilemma: How to Attack the Competition Without Alienating His Customer*, 2 J. OF CONSUMER MARKETING 67, 68-69 (1985) (comparative advertising naming specific competing brands is "increasingly used to differentiate a product or to introduce a new product name into the market").

[35] *See* Morton Schnabel, *Conscious Parallelism and Advertising Themes: The Case for 'Comparative' Advertising*, 7 ANTITRUST L. & ECON. REV. 11, 16 (1974-75) (comparative advertising may "reduce entry barriers in those situations where it is in fact conscious parallelism that is dictating the choices being made in this regard by a group of oligopoly firms.").

[36] For example, McDonald's at one time urged others in the industry to avoid comparative nutritional advertising. *See* Scott Hume, *Mac Chief Explodes 'Burger Wars'*, ADVERTISING AGE, Apr. 14, 1986, at 3, 3 (president of McDonald's Corporation, the leading fast food company, argues that continued used of comparative advertising would be destructive to "the restaurant industry and invite more attacks by nutrition extremists and the press"); Mark Schoifet, *Quinlan Urges Halt in Comparative Ads*, NATION'S RESTAURANT NEWS, Apr. 21, 1986, at 1, 1 (McDonald's opposes comparative advertising because it helps fuel attacks against fast food by "health-oriented consumer groups and a sensationalist press" and contributes to a negative mindset about fast food). McDonald's eventually responded to the competitive pressures and now posts nutritional information in its franchises.

for the business of an informed minority is often sufficient to provide benefits for all consumers.[37]

B. The Justification for Market Intervention

Comparative advertising benefits consumers only if it conveys truthful information.[38] While truthful information empowers consumers to maximize utility, erroneous information may lead them to make incorrect decisions.[39] In this respect, false comparative advertising can distort the market and could even drive superior products from the market.[40] Thus, deceptive advertising benefits no one — except perhaps the party engaging in it.

The FTC's recent analysis of nutritional advertising illustrates the public policy risks of false comparative drug advertising. The FTC staff has noted that deceptive health claims can damage the consumer in at least three ways. First, false claims may induce consumers to change their diet in a way that actually harms their health. Second, false claims may discourage consumers from making essential dietary changes or seeking essential medical treatment. Finally, false claims may economically injure consumers if they pay a premium price for a product that should not command one.[41]

As the primary federal agency charged with policing truth in the marketplace, the FTC recognizes that it must protect consumers from false advertising without discouraging truthful advertising.[42] Because truthful advertising is valuable to consumers, FTC regulation must be fine-tuned to screen out deceptive information without stifling the dissemination of truthful information.[43]

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[37] *See* Schnabel, *supra* note 35, at 16 (emphasis added).

[38] Robert Pitofsky, *Advertising Regulation and the Consumer Movement*, *in* ISSUES IN ADVERTISING: THE ECON. OF PERSUASION 27, 28 (David G. Tuerck ed., 1978).

[39] *Id.* at 28-29.

[40] *Id.* at 28-34, 39.

[41] *Comments Regarding Health Messages*, *supra* note 22, at 10-11.

[42] The FTC staff has observed:

> One of the FTC's major efforts is to regulate national advertising in a way that protects consumers from deception, but at the same time does not chill or prevent dissemination of truthful ads. The FTC has developed widely accepted standards for the regulation of deceptive advertising with minimum disruption to the dissemination of truthful information.

Id. at 2 (footnotes omitted).

[43] *Id.* In addressing the future of health claims relating to foods, therefore, the FTC staff acknowledged that, "[f]rom a public policy standpoint, it is important to

Economists and other commentators have long debated the value of regulatory efforts to control deceptive advertising. Some have argued that regulation is essential to address the market's failure to control false advertising.[44] Others, however, have suggested that the costs of regulation have more than offset its benefits.[45] Still other commentators believe that the marketplace itself deals best with false advertising. Simply put, if consumers find that a product does not live up to its advertising, they will not buy that product again.[46]

A laissez-faire approach may suffice to regulate advertising for many goods, but it would not be an acceptable approach to false advertising with respect to medications. Drugs are true "credence" goods because they possess qualities that cannot be evaluated through normal use. The assessment of a drug's qualities normally requires complex, time-consuming, and costly studies.[47] Most economists agree that regulation of advertising is necessary when the social costs of inaccurate or inadequate information are high and the consumer is unable to discern the truth.[48] These circumstances unquestionably apply in the case of

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balance the benefits and risks of allowing food manufacturers greater latitude to make health claims on labels. The most important risk is that some deceptive claims will also be made." *Id.* at 10.

44 *See* Robert Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 HARV. L. REV. 661, 664-65 (1977).

45 *See* R.H. Coase, *Advertising and Free Speech*, 6 J. LEGAL STUD. 1, 11-13 (1977). One economist, referring to the FTC's regulation of advertising, has argued:

> [T]he FTC bought little consumer protection in exchange for the more than $4 million it expended in the area of fraudulent and unfair marketing practices, and the millions more that it forced the private sector to expend in litigation and compliance. Besides wasting money on red herrings, it inflicted additional social costs of unknown magnitude by impeding the free marketing of cheap substitute products, including foreign products of all kinds, fiber substitutes for animal furs, costume jewelry, and inexpensive scents; by proscribing truthful designations; by harassing discount sellers; by obstructing a fair market test for products of debatable efficacy; and by imposing on sellers the costs of furnishing additional information and on buyers the costs of absorbing that information.

RICHARD A. POSNER, REGULATION OF ADVERTISING BY THE FTC 21 (1973) (citations omitted).

46 *See* Michael R. Darby & Edi Karni, *Free Competition and the Optimal Amount of Fraud*, 16 J. LAW & ECON. 67 (1973).

47 *Id.* at 68-69.

48 PETER ASCH, CONSUMER SAFETY REGULATION 55 (1988); *see also* Ronald Hirshhorn, *Regulating Quality in Product Markets*, in THE REGULATION OF QUALITY 55, 57-60 (Donald N. Dewees, ed., 1983) (with respect to credence goods, consumers are ill-equipped to evaluate product claims and to reach informed decisions regarding their quality).

drugs:

> The most obvious examples [of credence goods requiring government regulation] occur in food and drug markets, where the consequences of unsafe products are exceptionally serious. While manufacturers do have safety incentives, they may be willing to incur risks that are socially unacceptable; and consumers have little ability to obtain or interpret risk information beyond that which the manufacturers supply.[49]

When the market cannot reasonably be expected to function properly, some form of regulation is essential. In these instances, regulation may protect consumers by ensuring truth in advertising.[50] We first address direct regulation of drug advertising by the federal government. The balance of this article then focuses on a complementary system of indirect regulation through private civil actions under the Lanham Act.

C. *Direct Regulation of Drug Advertising*

The FDA and FTC jointly regulate drug advertising.[51] The FDA exclusively regulates prescription-drug labeling and advertising. For OTC drugs, however, the FDA regulates labeling,

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[49] ASCH, *supra* note 48, at 55. The FTC Bureau of Competition has acknowledged that it is difficult for consumers to evaluate the veracity of health claims. *Comments Regarding Health Messages*, *supra* note 22, at 16.

[50] With credence goods, moreover, regulation enjoys several potential advantages:

> The government, in intervening in the information market, has several potential advantages. It can attain economies of scale in research of the kind just mentioned. It operates at reduced transaction costs as it can impose uniform rules on numerous parties who in private agreements could not come nearly as easily to such a result. The government may thus induce uniform pricing methods, uniform grading, and other forms of standardization.
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> The government may also force suppliers to divulge information that they would have kept from private agencies and use this information to certify the presence of qualities or features.

EJAN MACKAAY, ECONOMICS OF INFORMATION AND LAW 155 (1982).

[51] The FDA and FTC have concurrent jurisdiction over drug advertising. *See* 21 U.S.C. § 352 (1988) (setting forth FDA requirements for the labeling of drugs and devices); 21 U.S.C. § 355 (1988) (providing approval mechanism for new drugs); 15 U.S.C. § 45 (1988) (declaring FTC authority in prohibiting unfair methods of competition); 15 U.S.C. § 52 (1988) (prohibiting false advertising and deceptive acts or practices); 15 U.S.C. § 54 (1988) (providing for imposition of penalties for false advertising). *See also* Warner-Lambert Co. v. FTC, 361 F. Supp. 948 (D.D.C. 1973), *aff'd as modified*, 562 F.2d 799 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978) (FDA and FTC have concurrent jurisdiction with respect to labeling and advertising claims concerning over-the-counter drugs). The FDA and the FTC have, by agreement, divided the responsibility for the regulation of over-the-counter drugs. *See infra* note 52 and accompanying text.

while the FTC regulates advertising.[52]

In 1975, the FDA adopted extensive regulations concerning prescription drug advertising. These regulations are designed, among other things, to insure that claims are supported by credible scientific evidence.[53] Under the Federal Food, Drug and Cosmetic Act (FD&CA), the FDA may consider a drug to be misbranded[54] and seize it, if the drug's advertising violates these regulations.[55] The FDA may also seek injunctive relief[56] or criminal penalties,[57] although the Agency has rarely invoked these powers. It has instead successfully resolved disputed claims through negotiations with pharmaceutical manufacturers. The FDA has assisted industry in complying voluntarily with its advertising regulations by publishing a number of comparative drug advertising guidelines.[58]

The FTC, on the other hand, has litigated many false advertising claims and has articulated a clear analytical framework. In essence, the FTC will act when it believes that a material representation, omission or practice is likely to mislead a reasonable consumer.[59] The FTC seeks to balance the advantages of truthful advertising against the costs of regulation.[60]

The FTC first addressed the need for reasonable evidence to

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52 36 Fed. Reg. 18,539 (1971).

53 21 C.F.R. § 202.1 (1991). Some of these regulations are addressed *infra* at notes 84-101 and accompanying text.

54 21 U.S.C. § 352 (1988).

55 21 U.S.C. § 334 (1988).

56 21 U.S.C. § 332(a) (1988).

57 21 U.S.C. § 333 (1988).

58 *See Comparative Drug Advertising Working Guidelines*, F.D.A. Letter (July 6, 1982). *See also Clarification of FDA Policy on "Institutional," "Corporate" or "Health Message" Advertising Practices* (FDA Sept. 8, 1985); Policy Guidance, *Pre-Publication Review of Promotional Materials* (FDA Sept. 1985); David Banks, *Excerpt of Comments Regarding Prescription Drug Advertising*, RAPS Annual Meeting (Sept. 27, 1988); Lloyd G. Millstein, *FDA Policy on Comparative Prescription Drug Advertising*, 17 DRUG INFO. J. 63, 65 (1983) ("The FDA's primary purpose is to ensure that prescription drug advertising is not false or misleading. We want to be able to assure the public that the physician does not prescribe on the basis of promotion or less than full information. Because of the sensitive nature of medical and pharmaceutical information, the need to adhere to strict government regulations is vital. There is no room for disputed or less-than-factual information.").

59 *See FTC Policy Statement on Deception, reprinted in* 4 ANTITRUST AND TRADE REG. REP. (CCH) ¶ 13,205, at 20, 911-20, 917 (Oct. 14, 1983).

60 At one time, the FTC prohibited advertising that might potentially mislead anyone. The test came to be known as the "fool's test" because the FTC insisted on advertising so clear that, "in the words of the prophet Isaiah, 'wayfaring men, though fools, shall not err therein.' " Charles of the Ritz Distrib. Corp. v. FTC, 143 F.2d 676, 680 (2d Cir. 1944). The FTC abandoned the fool's test in In the Matter of Heinz W. Kirchner, 63 F.T.C. 1282 (1963), *aff'd*, 337 F.2d 751 (9th Cir. 1964).

support advertising claims in *In the Matter of Heinz W. Kirchner*.[61] In that case, Kirchner promoted a swimming-aid device as "safe" to the extent that even poor swimmers would be unsinkable. But Kirchner made those claims without any meaningful evidence to support them. The Commission found that Kirchner marketed a potentially dangerous product and claimed that it was safe and unsinkable without first determining whether the product possessed those qualities.[62]

The FTC held that Kirchner could not make such unproven assertions in complete disregard of the consumer's health and safety. The FTC concluded:

> [A]n advertiser is under a duty, *before* he makes any representation which, if false, could cause injury to the health or personal safety of the user of the advertised product, to make reasonable inquiry into the truth or falsity of the representation. *He should have in his possession such information as would satisfy a reasonable and prudent businessman, acting in good faith, that such representation was true.* To make a representation of this sort, without such minimum substantiation, is to demonstrate a reckless disregard for human health and safety, and is clearly an unfair and deceptive practice.[63]

A decade later, the FTC addressed the "minimum substantiation" requirement in the context of pharmaceutical advertising. In *In the Matter of Pfizer, Inc.*,[64] Pfizer's advertisements claimed that its sunburn treatment "relieves pain *fast*" and "actually *anesthetizes nerves* in sensitive sunburned skin."[65] The FTC enforcement staff argued that Pfizer could not make these claims without first conducting a reasonable investigation to substantiate its claims.[66] The FTC staff argued, moreover, that controlled scientific tests were required to satisfy the reasonable investigation requirement.

Pfizer agreed that manufacturers must first conduct a reasonable investigation before making advertising claims. Pfizer conceded, moreover, that it had not performed any scientific tests. But Pfizer argued that it had performed a reasonable investigation by collecting a substantial body of pre-existing medical literature and clinical data demonstrating the efficacy of its product.[67] The FTC

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61 63 F.T.C. 1282 (1963).
62 *Id.* at 1295.
63 *Id.* at 1294 (emphasis added).
64 81 F.T.C. 23 (1972).
65 *Id.* at 24 (emphasis in original).
66 *Id.* at 54.
67 *Id.* at 41-42.

surveyed the state of the art and concluded that, in fact, most scientists would have accepted the evidence marshalled by Pfizer to support its claims. Accordingly, the FTC rejected the proposition of its staff that controlled scientific tests were essential to satisfy the "reasonable investigation" requirement as a matter of law.

The FTC also recognized that general principles accepted by the community of pharmacologists to evaluate efficacy claims coincided with the FDA's principles governing efficacy determinations. Therefore, in determining whether the advertiser had conducted a reasonable investigation of its efficacy claims, the FTC could use the FDA's standards. Indeed, the FTC wrote:

> [I]t would not seem reasonable to suppose that the [FTC] would deliberately take a position disregarding clinical experience *particularly since that position would be contrary to the position taken by the [FDA] in the adequacy testing of drugs*. It would seem, therefore, that the [FTC] under its announced policies would *defer to the agency that is specifically charged by Congress with determining the adequacy and safety of drug products*.[68]

Through the 1970s, the FTC continued to insist that pharmaceutical companies have a "reasonable basis" for medical claims in OTC drug advertising. In *In the Matter of Porter & Dietsch, Inc.*,[69] the respondents advertised that their OTC drug constituted "[a] PROVEN and SOUND method" for weight reduction with "clinically tested ingredients."[70] The respondents, however, conceded that they had no scientific data or other information to support their weight-loss representations.[71] In deciding to enjoin the advertisements, the FTC reiterated its position that pharmaceutical manufacturers must have a reasonable basis for their claims.[72]

An Administrative Law Judge (ALJ) recently elaborated on the FTC's approach to these issues in *In the Matter of Schering Corp.*[73] In that case, Schering advertised "Fibre Trim" as an effective weight-loss and weight-maintenance product. The advertisements included general claims about Fibre Trim's health benefits[74] but did not refer to the substantive basis for the claims. Because the advertisements contained objective statements about Fibre Trim's weight reducing

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68 *Id.* at 55 (footnotes omitted) (emphasis added).

69 90 F.T.C. 770 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980).

70 *Id.* at 865.

71 *Id.* at 868.

72 *Id.* at 866.

73 No. 9232 (Initial Decision, Sept. 16, 1991).

74 *Id.* at 68.

qualities, the ALJ required Schering to have a reasonable basis for the claims.[75] Because the advertisements implied that Schering had a scientific basis for the claims, Schering was required to substantiate them with proof acceptable to the relevant scientific community.[76]

The ALJ then considered the nature of the required substantiation.[77] Because Fibre Trim's advertisements contained claims of "health benefits," the ALJ found that "a relatively high level of substantiation, typically scientific tests" would be required because health representations comprise "credence" claims.[78] The ALJ found that, given the revenues generated by the product, Schering could reasonably be expected to conduct two well-controlled clinical trials to substantiate its claims. The ALJ noted that the benefit of truthful health claims was obvious, given that obesity was a large public health problem, and that, because of Fibre Trim's high cost, a false claim would substantially harm consumers. The ALJ credited expert testimony indicating that, at a minimum, two clinical tests should be conducted to establish the validity of Fibre Trim's claims.[79] Finally, the ALJ reviewed Schering's data and concluded that the studies Schering had relied on to substantiate its claims were fundamentally flawed.[80]

In dealing over the years with *implied* substantiation claims, like

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75 *Id.* (citing Thompson Medical Co. v. Federal Trade Commission, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987)).

76 *Id.*

77 Because Fibre Trim's advertising did not refer to the scientific evidence for its claims, the ALJ stated that the following factors determined the adequacy of the substantiation: (1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; *and* (6) the nature of the substantiation experts in the field would agree is reasonable. *Id.* (citing In the Matter of Pfizer, Inc., 81 F.T.C. 23, 64 (1972); *Thompson Medical*, 104 F.T.C. at 840).

78 *Id.* at 68-69 (quoting *Thompson Medical*, 104 F.T.C. at 822 n.60). The ALJ noted:

> Because of the placebo effect, it is difficult for consumers to evaluate Schering's Fibre Trim claims even if they consume it for an extended period of time. Credence claims like these which are "the sort that consumers would not be able to verify easily for themselves" therefore require a high standard of proof such as scientifically adequate clinical trials.

Id. at 69 (quoting *Thompson Medical*, 104 F.T.C. at 822-23).

79 *Id.*

80 *Id.* at 70-71. The ALJ noted that one of Schering's own scientists doubted whether the data would support an application for a new prescription drug or for OTC marketing. *Id.* at 42. He also cited specific findings by an FDA advisory expert panel that conflicted with Schering's claims. *Id.* at 45.

those in *In re Pfizer, Inc.* and *In re Schering Corp.*, the FTC has stressed that its decision to act in any particular case depends on a number of factors relevant to the benefits and costs of substantiating a particular claim.[81] In essence, the FTC will be more inclined to act when false health claims pose substantial risks to consumers and less inclined to act when questionable claims entail only de minimis economic concerns.[82] In short, the FTC will require greater substantiation as the risk to the consumer increases.[83] When it acts, moreover, the FTC will rely heavily, if not conclusively, on FDA standards.

D. Establishment Claims

The FTC does not use a flexible standard to evaluate *express* establishment claims. In an express claim, the advertiser actually represents that it has a particular level of substantiation. The FTC insists that these claims be supported by the same level of substantiation that they communicate to the consumer. Thus, if an advertisement states that a particular level of proof supports

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81 *FTC Policy Statement Regarding Advertising Substantiation Program*, 49 Fed. Reg. 30,999 (1984).

82 *See Comments Regarding Health Messages, supra* note 22, at 11-12 ("Because the potential benefits and risks of particular claims vary widely, we believe that [the regulation] can best be accomplished by a flexible approach to evaluating individual claims rather than a rigid rule that applies to every possible claim. This is particularly true for the area of deceptive health claims on food labeling because some unsubstantiated claims could result in health injury while others present only de minimis risks of economic harm.").

83 *Id.* at 16 ("Under this flexible approach, the required level of substantiation rises with the potential for consumer injury should the claim turn out to be false. For example, where the particular product claim raises concerns about possible injury to the health or safety of consumers or will be difficult or impossible for consumers to assess for themselves, the [FTC] requires a relatively high level of substantiation."). Thus, the FTC will consider, on a case by case basis, the risk of an erroneous claim to the public health:

> [F]or example, when FTC officials commented on the Kellogg's All-Bran ad in 1985 they noted that they were aware of no grave health or safety risks that flowed from choosing All-Bran over another breakfast cereal. In contrast, there are instances where consumption of the food as advertised does raise health or safety concerns. In In re Estee, Inc. [102 F.T.C. 1804 (1983)], for example, the Commission alleged claims that Estee's advertising encouraged diabetics to consume food without adequate substantiation about how those foods affected blood sugar levels. [Citation omitted.] In such cases, the health or safety risk obviously demands a high level of substantiation. . . . The flexible substantiation doctrine used by the Commission would allow the FDA to deal firmly with these cases without jeopardizing truthful claims.

Id. at 20 n.42.

the product's claims, *e.g.*, that three major clinical studies establish a particular representation, then that level of proof must exist to substantiate the representation.[84]

The FTC first addressed an express establishment claim concerning a drug's efficacy in *In the Matter of American Home Products Corp.*[85] In that case, American Home Products Corp. (American) claimed that Anacin's superiority had been proven by scientific tests.[86] The FTC found that American could not substantiate its claim. The FTC noted that the express claim of "proven" superiority would mislead consumers into believing that scientific tests actually showed Anacin to be the most effective OTC analgesic.

The FTC likewise recognized that it would be appropriate to consider FDA regulations governing scientific evidence when evaluating these establishment claims.[87] The FTC credited expert testimony, received in the course of the administrative proceeding, indicating that the FDA's regulations reflect good scientific practice.[88]

The FTC further clarified its position on establishment claims in two later cases dealing with pharmaceutical advertising. In *In the Matter of Bristol-Myers Co.*,[89] the manufacturer of Bufferin advertised that "[s]cientific tests show that . . . Bufferin delivers twice as much pain reliever as simple aspirin."[90] It also advertised that "[n]ew clinical evidence says Excedrin [is better than aspirin]. In a major hospital study, two Excedrin work better in relieving pain than twice as many aspirin tablets."[91] The FTC noted that words such as "medically recognized" and "clinic tested" would lead consumers to believe that the claims have been established by scientific research generally acceptable to the relevant scientific or medical community.[92]

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84 *Comments Regarding Health Messages*, *supra* note 22, at 13. *See also FTC Policy Statement Regarding Advertising Substantiation Program*, 49 Fed. Reg. 30,999 (1984) ("When the substantiation claim is express (e.g., 'tests prove', 'doctors recommend', and 'studies show'), the Commission expects the firm to have at least the advertised level of substantiation.").

85 98 F.T.C. 136 (1981), *aff'd*, 695 F.2d 681 (3d Cir. 1982), *modified*, 103 F.T.C. 528 (1984).

86 *Id.* at 363.

87 *Id.* at 378.

88 *Id.* at 381-82.

89 102 F.T.C. 21 (1983), *aff'd sub nom.* Bristol-Myers Co. v. FTC, 738 F.2d 554 (2d Cir. 1984), *cert. denied*, 469 U.S. 1189 (1985).

90 *Id.* at 324.

91 *Id.* at 325.

92 *Id.* at 330.

In resolving this and similar cases,[93] the FTC borrowed liberally from FDA regulations. Thus, like the FDA, the FTC required tests conducted pursuant to a written protocol by independent and experienced investigators using randomized treatment and control groups.[94] The tests had to be "double-blinded," so that neither the investigator nor the subject knew whether active drugs or placebos were being utilized.[95] Further, when the studies were completed, data had to be statistically and clinically evaluated using generally accepted scientific methodologies.[96] Finally, to support a comparative efficacy claim, at least two valid studies were required.[97] The FTC explained that it relied on the FDA's criteria because they reflected those accepted in the relevant scientific community.[98]

The FTC next addressed establishment claims in pharmaceutical advertising in *In the Matter of Thompson Medical Co.*[99] There, Thompson Medical advertised that its topical analgesic drug had been shown to be more effective than orally-ingested aspirin. The FTC found some of Thompson Medical's claims to be false because the claims were not supported by the appropriate scientific evidence. The Agency noted:

> 'Establishment claims' are claims that the efficacy of a drug has been scientifically prove[n], *i.e.*, 'established.' In our three recent cases, we stated that we require such claims to be substantiated by evidence sufficient to satisfy the relevant scientific community of the claim's truth. We further stated that the appropriate level of substantiation for other claims would be determined by considering factors such as the harm to consumers if the claim were false.[100]

As in prior cases involving establishment claims, the FTC relied on

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93 *See* In the Matter of Sterling Drugs, Inc., 102 F.T.C. 395 (1983), *aff'd sub nom.* Sterling Drugs, Inc. v. F.T.C., 741 F.2d 1146 (9th Cir. 1984), *cert. denied*, 470 U.S. 1084 (1985).

94 *Bristol-Myers*, 102 F.T.C. at 334-37; *Sterling Drugs*, 102 F.T.C. at 763-71.

95 *Bristol-Myers*, 102 F.T.C. at 335; *Sterling Drugs*, 102 F.T.C. at 803.

96 *Bristol-Myers*, 102 F.T.C. at 336; *Sterling Drugs*, 102 F.T.C. at 803.

97 *Bristol-Myers*, 102 F.T.C. at 337; *Sterling Drugs*, 102 F.T.C. at 803.

98 *Bristol-Myers*, 102 F.T.C. at 339.

99 104 F.T.C. 648 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

100 *Id.* at 821-22 n.59 (relying on In the Matter of American Home Products Corp., 98 F.T.C. 136 (1981), *aff'd sub nom.* American Home Products Corp. v. Johnson & Johnson, 695 F.2d 681 (3d Cir. 1982), *modified*, 103 F.T.C. 528 (1984); In the Matter of Sterling Drugs, Inc., 102 F.T.C. 395 (1983), *aff'd sub nom.* Sterling Drugs, Inc. v. F.T.C., 741 F.2d 1146 (9th Cir. 1984), *cert. denied*, 470 U.S. 1084 (1985); In the Matter of Bristol-Myers Co., 102 F.T.C. 21 (1983), *aff'd sub nom.* Bristol-Myers Co. v. F.T.C. 738 F.2d 554 (2d Cir. 1984), *cert. denied*, 469 U.S. 1189 (1985)).

FDA criteria to evaluate the quality of the scientific evidence cited to support the advertising claims.[101]

The FTC's approach to the regulation of establishment claims effectively balances the competing interests. The FTC seeks to protect the public from false and deceptive advertising while simultaneously encouraging the dissemination of useful information. In evaluating claims of efficacy and safety, moreover, the FTC is appropriately guided by the scientific standards of the FDA, the Agency primarily responsible for regulating pharmaceutical products.

When a pharmaceutical manufacturer advertises that its product enjoys scientifically-proven superiority, whether in terms of efficacy or safety, the claim conveys powerful information. If the company lacks the scientific evidence to establish the claim, the company misleads the public and may profoundly harm consumers and competition in the process.

III. PRIVATE REGULATION OF FALSE ADVERTISING UNDER THE LANHAM ACT

Short of governmental action or a competitor's agreement to abide by industry standards, an aggrieved manufacturer has only one effective remedy to combat false comparative advertising: an action under section 43(a) of the Lanham Act.[102] Despite the

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101 *Id.* at 828-29.

102 15 U.S.C. § 1125(a) (1988). Section 1125(a) provides:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which —
>
> (1) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
>
> (2) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a) (1988).

For general discussions of false advertising claims under Section 43(a) of the Lanham Act, *see* Paul E. Pompeo, *To Tell the Truth: Comparative Advertising and Lanham Act Section 43(a)*, 36 CATH. UNIV. L. REV. 565 (1987); Garrett J. Waltzer, *Monetary Relief for False Advertising Claims Arising Under Section 43(a) of the Lanham Act*, 34 U.C.L.A. L. REV. 953 (1987); Gary S. Marx, *Section 43(a) of the Lanham Act: A Statutory Cause of Action for False Advertising*, 40 WASH. & LEE L. REV. 383 (1983); Thomas J. Donegan, Jr., *Section 43(a) of the Lanham Act as a Private Remedy for False Advertising*, 37 FOOD DRUG COSM. L.J. 264 (1982).

Lanham Act's long history, this remedy did not reach its full potency until 1988 and has not yet been fully tested in challenging comparative advertising premised on false scientific establishment claims.

A. The Evolution of Lanham Act Jurisprudence

Trademark law protects the psychological function of merchandising symbols.[103] Even though false advertising may weaken the commercial magnetism of another's trademark, federal law did not always provide an effective remedy against it. In fact, courts historically limited the reach of trademark law to "palming-off" claims — those involving false designations of origin. Many early cases construed the Lanham Act to go no further.[104]

In 1954, the courts broke free of the palming-off paradigm and extended the Lanham Act to false advertising. In *L'Aiglon Apparel, Inc. v. Lana Lobell, Inc.*,[105] the plaintiff, a dress manufacturer, advertised a dress in a national advertising campaign. The defendant offered an inferior dress at a lower price but used a picture of the plaintiff's dress in its advertising. The plaintiff did not claim that the defendant was palming-off its inferior product. Rather, the plaintiff argued that the defendant was misleading consumers by implying that they could obtain a dress similar to the plaintiff's but for less money. The district court, finding no palming-off claim, dismissed the complaint.

The Third Circuit reversed. The court broadly held that the

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103 In Mishawaka Rubber & Woolen Mfg. Co. v. S.S. Kresge Co., 316 U.S. 203 (1942), the Supreme Court explained the nature of trademark law in these classic terms:

> The protection of trade-marks is the law's recognition of the psychological function of symbols. If it is true that we live by symbols, it is no less true that we purchase goods by them. A trade-mark is a merchandising short-cut which induces a purchaser to select what he wants, or what he had been led to believe he wants. The owner of a mark exploits this human propensity by making every effort to impregnate the atmosphere of the market with the drawing power of a congenial symbol. Whatever the means employed, the aim is the same — to convey through the mark, in the minds of potential customers, the desirability of the commodity upon which it appears. Once this is attained, the trade-mark owner has something of value. If another poaches upon the commercial magnetism of the symbol he has created, the owner can obtain legal redress.

Id. at 205.

104 *See* Samson Crane Co. v. Union Nat. Sales, Inc., 87 F. Supp. 218 (D. Mass. 1949); Chamberlain v. Columbia Pictures Corp., 186 F.2d 923 (9th Cir. 1951).

105 118 F. Supp. 251 (E.D. Pa. 1953), *rev'd*, 214 F.2d 649 (3d Cir. 1954).

Lanham Act prohibited unfair competition through false advertising as well as palming-off. In sweeping terms, the court found that Congress, in adopting section 43(a), created a federal statutory tort similar to the common law tort of unfair competition.[106]

Despite the Third Circuit's breakthrough analysis in *L'Aiglon Apparel*, other precedents continued to limit the Lanham Act's potential to control false advertising, particularly false comparative advertising. In *Bernard Food Industries v. Dietene Co.*,[107] for example, Dietene distributed a comparison sheet that listed the ingredients of its custard and a custard manufactured by Bernard Food. Dietene incorrectly indicated that Bernard Food's custard did not contain any egg. The Seventh Circuit rejected Bernard Food's false advertising claim, finding that "false advertising or representations made by a defendant about a plaintiff's product are not covered by section 43(a)."[108]

The holding in *Bernard Food* was often criticized (and sometimes avoided) in the almost twenty years that it remained valid law. In *Skil Corp. v. Rockwell International Corp.*,[109] for example, Skil challenged Rockwell's comparative advertising campaign concerning the companies' competing drill and jigsaw products. Rockwell claimed product superiority based on "test data generated by an independent product testing organization."[110] Rockwell, relying on *Bernard Food*, moved to dismiss Skil's Lan-

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106 In rejecting the defendant's argument that Congress intended to limit the Lanham Act to palming-off claims, the Third Circuit wrote:

> [W]e reject this entire approach to the statute. We find nothing in the legislative history of the Lanham Act to justify the view that this section is merely declarative of existing law. . . . It seems to us that Congress has defined a statutory civil wrong of false representation of goods in commerce and has given a broad class of suitors injured or likely to be injured by such wrong the right to relief in the federal courts. This statutory tort is defined in language which differentiates it in some particulars from similar wrongs which have developed and have become defined in the judge made law of unfair competition. Perhaps this statutory tort bears closest resemblance to the already noted tort of false advertising to the detriment of a competitor, as formulated by the American Law Institute out of materials of the evolving common law of unfair competition. . . . But however similar to or different from pre-existing law, here is a provision of a federal statute which, with clarity and precision adequate for judicial administration, creates and defines rights and duties and provides for their vindication in the federal courts.

L'Aiglon Apparel, 214 F.2d at 651 (citations omitted).

107 415 F.2d 1279 (7th Cir. 1969), *cert. denied*, 397 U.S. 912 (1970).

108 *Id.* at 1283 (citations omitted).

109 375 F. Supp. 777 (N.D. Ill. 1974).

110 *Id.* at 780.

ham Act claim. The court concluded, however, that *Bernard Food* did not govern because Rockwell's comparative claims involved more than simple representations "made by a defendant about a plaintiff's product." The court reasoned that any comparative advertising *necessarily* involves some statement about *both* products.[111]

The *Skil* court correctly characterized the holding in *Bernard Food* as illogical.[112] Congress later agreed. In the *Trademark Law Revision Act of 1988*,[113] Congress expressly amended section 43(a) to overrule *Bernard Food*.[114] Congress concluded that the holding was "illogical on both practical and public policy levels and that the public policy of deterring acts of unfair competition will be served if [s]ection 43(a) is amended to make clear that misrepresentations about another's products are as actionable as misrepresentations about one's own."[115]

Congress also clearly indicated that it had adopted the Lanham Act in general, and section 43(a) in particular, to protect competitors *and consumers*.[116] Congress noted that "[t]rademark law protects the public by making consumers confident that they can identify brands they prefer and can purchase those brands without being confused or misled."[117]

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111 *Id.* at 782-83. The court reasoned that, if a competitor makes a false statement about another's product in comparative advertising, he is also falsely claiming that his own product is superior. *Id.* at 782 n.10. Hence, the competitor necessarily makes some misrepresentation about its own product. *Id.*

112 *Id.* ("With due respect to the Court [in *Bernard Food*], it does not seem logical to distinguish between a false statement about the plaintiff's product and a false statement about the defendant's product in a case where the particular statement is contained in comparison advertising by the defendant, such that in the first instance the plaintiff does not have a cause of action whereas in the latter he does.").

113 Pub. L. No. 100-667, 102 Stat. 3935 (1988).

114 *See* S. REP. No. 515, 100th Cong., 2d Sess. 7 (1988), *reprinted in* 1988 U.S.C.C.A.N. 5577, 5603-04.

115 *Id.* at 5603.

116 *See id.* at 5577 ("The purpose of the Trademark Law Revision Act of 1988 is to . . . improve the law's protection of the public from counterfeiting, confusion, and deception.").

117 *Id.* at 5580. Some courts have correctly indicated that section 43(a) actions are not the proper vehicle through which to vindicate *solely* the public's interest in health and safety. *See* American Home Products Corp. v. Johnson & Johnson, 672 F. Supp. 135, 145 (S.D.N.Y. 1987). With some showing of competitive injury, however, the courts should consider the public's interest in health and safety. Congress explicitly reaffirmed that proposition in the legislative history to the *Trademark Revision Act of 1988*. *See* S. REP. No. 515, *supra* note 114, at 5577 ("The purpose of the [Act] is to . . . improve the law's protection of the public. . . .").

Moreover, in a case of comparative drug advertising, where consumers may be confronted with a choice of two competing medications, it is difficult to envision an instance of consumer confusion without concomitant competitive injury. The com-

Many cases under the Lanham Act explicitly consider the consumer's welfare,[118] particularly when dealing with claims involving products vital to consumer well-being.[119] A competitor's interest in fair competition and the public's interest in truthful advertising are coterminous.[120] Under section 43(a), therefore, a plaintiff-competitor, while vindicating its own interests, simultaneously serves as the "vicarious avenger of the defendant's customers."[121] This is true, of course, even though Congress may not have given consumers standing to sue *in their own right* under section 43(a).[122]

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petitive injury necessarily derives from the consumer confusion. At the same time, it is difficult to envision consumer confusion that does not result in competitive injury. Therefore, the sterile proposition underlying this line of authority seems to conflict with the legislative history and makes very little sense as a matter of law. *See* Upjohn Co. v. American Home Products Corp., 598 F. Supp. 550, 557-58 (S.D.N.Y. 1984); Ciba-Geigy Corp. v. Thompson Medical Co., Inc., 672 F. Supp. 679, 690 (S.D.N.Y. 1985).

118 *See, e.g.*, Coca-Cola Co. v. Proctor & Gamble Co., 822 F.2d 28, 31 (6th Cir. 1987) ("Protecting consumers from false or misleading advertising . . . is an important goal of the [Lanham Act] and a laudable public policy to be served."); Vidal Sassoon v. Bristol-Myers Co., 661 F.2d 272, 273 (2d Cir. 1981) ("We are . . . reluctant to accord the language of § 43(a) a cramped construction, lest rapid advances in advertising and marketing methods outpace technical revisions in statutory language and finally defeat the clear purpose of Congress in protecting the consumer."); Hobart Corp. v. Welbilt Corp., No. 1:89CV1726, 1989 U.S. Dist. LEXIS 14447, at *33 (N.D. Ohio Oct. 4, 1989). ("The statute at issue here, the Lanham Act, is designed to protect the consuming public.").

119 *See, e.g.*, McNeilab, Inc. v. American Home Products Corp., 848 F.2d 34, 35 (2d Cir. 1988) (Lanham Act claims involving advertising for over-the-counter medications will "protect the public from inaccurate safety claims"); Syntex Laboratories, Inc. v. Norwich Pharmacal Co., 437 F.2d 566, 569 (2d Cir. 1971) (advertising claims involving pharmaceutical products warrant a "stricter standard" when determining trademark infringement); *cf.* Energy Four, Inc. v. Dornier Medical Systems, Inc., 765 F. Supp. 724, 735 (N.D. Ga. 1991) (false advertising claims concerning medical devices warrant corrective advertising in view of the inherent public health concerns); Upjohn Co. v. Riahom Corp., 641 F. Supp. 1209, 1225 (D. Del. 1986) (injunction warranted in Lanham Act false advertising action involving hair growth product because defendants were "thumbing their noses at United States drug regulations").

120 Albert Robin & Howard B. Barnaby, Jr., *Comparative Advertising: A Skeptical View*, 67 TRADEMARK REP. 358, 361 (1977) ("When the public is protected from confusion as a result of trademark infringement litigation, the trademark owner is protected in his good will.").

121 Ely-Norris Safe Co. v. Mosler Safe Co., 7 F.2d 603 (2d Cir. 1925) (Learned Hand, J.), *rev'd on other grounds*, 273 U.S. 132 (1927). *See generally*, Robert S. Saunders, *Replacing Skepticism: An Economic Justification for Competitors' Actions for False Advertising Under Section 43(a) of the Latham Act*, 77 VA. L. REV. 563 (1991) (arguing that consumers benefit when competitors police the market-place of information through private actions).

122 Standing to sue, and the interests served by a type of suit, may differ. Therefore, the fact that a consumer does not have a right to sue under the Lanham Act

B. Elements of a Modern Lanham Act Claim for False Advertising

A modern Lanham Act claim for false advertising is governed by five essential elements. A plaintiff must show:

> (1) that the defendant has made false or misleading statements. . . ; (2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; (3) that the deception is material in that it is likely to influence purchasing decisions; (4) that the advertised goods traveled in interstate commerce; and (5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.[123]

The first element itself entails two distinct inquiries: what is the message, and is it false or misleading?

In determining what message is conveyed by an advertisement, a court may consider how a particular term in the advertisement is commonly used and understood. If the advertisement is directed to those in a particular field or profession, the court may consider how the words in the advertisement would be commonly understood by that field or profession.[124] If the advertisement is directed to the public, the court may consider how the words used in the advertisement would be commonly understood by the public.[125] The court

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does not mean that his or her interests (as a consumer) are not served by the Act; nor does it mean that the standards governing a claim under the Act should not be defined with the interests of consumers in mind.

[123] U.S. Healthcare, Inc. v. Blue Cross of Greater Philadelphia, 898 F.2d 914, 922-23 (3d Cir.), *cert. denied*, 111 S. Ct. 58 (1990) (quoting Max Daetwyler Corp. v. Input Graphics, Inc., 545 F. Supp. 165, 171 (E.D. Pa. 1982)).

[124] *See, e.g.*, Hobart Corp. v. Welbilt Corp., No. 1:89CV1726, 1989 U.S. Dist. LEXIS 14447, *1 (N.D. Ohio Oct. 4, 1989) (mixing machine manufacturer claimed its machine had higher "yield" and produced more "product" in mixing dough; to ascertain meaning of advertisement's reference to "yield" and "product," court considered how terms are used in the business of food preparation; court cited experts' testimony as evidence of how terms are commonly used and understood).

[125] In American Home Products Corp. v. Abbott Laboratories, 522 F. Supp. 1035, 1042 (S.D.N.Y. 1981), the court determined that an advertising claim that the defendant's OTC medication "stops pain immediately" was false "based on the meaning of the words, the context in which the words are used, both grammatical and commercial, and the intent with which the words are being used by this defendant." To determine the meaning of the words, the court referred to dictionaries and an understanding of the term "immediate" as "provided by the FDA drug panel report. . . ." *Id.* Thus, "[i]n the relevant context," the word "unambiguously" had a false meaning. *Id.* The court reasoned that "[t]he commercial context, like the grammatical, helps define the meaning of the phrase at issue." *Id.* at 1043.

Similarly, in Quaker State Oil Refining Corp. v. Burmah-Castrol, Inc., 504 F. Supp. 178, 180 (S.D.N.Y. 1980), the court found "false on its face" the statement that: "An independent lab test reveals that . . . Castrol does not lose viscosity" because, even though the study showed it did not permanently lose viscosity, it did so temporarily, and the ad "may be fairly read to mean that Castrol never loses

may also consider the context in which claims are made to ascertain their message.[126]

After determining what message is conveyed by a challenged advertisement, the court must then decide whether that message is false or misleading. The definition of a "false" claim would seem to be self-evident. The Lanham Act, however, does not allow an advertiser to mislead consumers with half-truths. Therefore, even if an advertisement is literally true, the plaintiff may still prevail by showing that consumers received a false impression about the product.[127] Courts often require survey data to determine whether an advertising claim leaves a false impression in its wake.[128]

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viscosity even temporarily. . . ." *See also* Upjohn Co. v. Riahom Corp., 641 F. Supp. 1209, 1223 (D. Del. 1986) (court decided what "patented" would likely mean to American consumer, and concluded that its "clear implication" was false); Tambrands, Inc. v. Warner-Lambert Co., 673 F. Supp. 1190, 1193 (S.D.N.Y. 1987) (court found that the "thrust of defendants' advertisements is false" and hence the advertisements were "false on their face").

Of course, the court must be fairly convinced that a technical definition comports with its common meaning. In Energy Four, Inc. v. Dornier Medical Systems, Inc., 765 F. Supp. 724, 729 (N.D. Ga. 1991), the defendant claimed, in comparative advertising, that the plaintiff's product was subject to "catastrophic failure." The plaintiff produced evidence, by a principal and an expert, indicating that "catastrophic failure was generally understood in the relevant medical community to mean a failure resulting in serious equipment damage or patient injury." The defendant, by contrast, relied on the definition of "catastrophic failure" found in an engineering dictionary ("a sudden failure without warning, as opposed to degradation failure"). The court rejected the dictionary definition, noting that the defendant had "presented no evidence that the dictionary definition reflected a common understanding among targeted consumers." *Id.* at 729-30.

126 The court may consider the necessary implications of the literal words. For example, in *Tambrands*, 673 F. Supp. at 1193-94, the court found that the "[d]efendants' advertisements are facially false in that they state by *necessary implication* that New E.P.T. Plus is a ten-minute test, when in fact the test requires at least thirty minutes for most women to obtain test results." *Id.* (The court further found that "material statements in the ad are facially false . . . by necessary implication" even though the ad "does not make the [facially false] statements *in haec verba*") (emphasis added). The court held that "the *thrust* of defendants' advertisements is false, and that even the qualifying words added to the advertising copy do not sufficiently modify the message to render the advertisements true." *Id.* at 1193 (emphasis added).

127 *Energy Four, Inc.*, 765 F. Supp. at 730.

128 When the court can simply look at the claim and find that it is false on its face, there is no need to determine how the message has been or will be understood in the marketplace. *See* Coca-Cola v. Tropicana Products, Inc., 690 F.2d 312, 317 (2d Cir. 1982) ("When a merchandising statement or representation is literally or explicitly false, the court may grant relief without reference to the advertisement's impact on the buying public.") (citations omitted); *Energy Four, Inc.*, 765 F. Supp. at 731 ("When representations are actually false, a court does not have to determine whether the representations are likely to create confusion.") (citing Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222 (3d Cir. 1990)).

By contrast, if the advertising claim is literally true, and there is a legitimate

Most disputes over comparative scientific establishment claims boil down to one dispositive issue: is the claim false on its face? The remaining elements of a Lanham Act claim may rarely be contested. A multi-million dollar comparative advertising campaign, based on a literally false scientific claim, will unquestionably influence purchasing decisions;[129] the false claim will "travel[] in interstate commerce;"[130] and the false claim will certainly cause competitive injury.[131]

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dispute about the ultimate meaning of the message, most courts require survey evidence to determine whether a substantial number of consumers will be misled. *See* Tyco Indus. v. Lego Systems, 5 U.S.P.Q. 2d 1023, 1030 (D.N.J. 1987) ("[W]here as here the issue is whether true statements are misleading or deceptive despite their truthfulness, it is not enough to place statements alone before the Court. The plaintiff must adduce evidence (usually in the form of market research or consumer surveys) showing how the statements are perceived by those who are exposed to them.") (quoting McNeilab Inc. v. American Home Products Corp., 501 F. Supp. 517, 575 (S.D.N.Y. 1980)); *cf.* Stiffel Co. v. Westwood Lighting Group, 658 F. Supp. 1103, 1112 (D.N.J. 1987) (survey evidence is critical because, if an advertisement is not false on its face, whether it is misleading "must be resolved by reference to representative reactions of the trade and consuming public"); *Quaker State*, 504 F. Supp. at 182 (surveys essential "[i]f an advertisement is not facially false" (quoting American Home Prod. Corp. v. Johnson & Johnson Corp., 577 F.2d 160, 165 (2d Cir. 1978)).

[129] Ordinarily, consumer reaction surveys are necessary to "supply evidence that the abusive advertisement was the cause of the plaintiff's potential lost sales or goodwill, thus indicating a likelihood of injury." Pompeo, *supra* note 102, at 575 (citing *Coca-Cola*, 690 F.2d at 317); *see also* Vidal Sassoon v. Bristol-Myers Co., 661 F.2d 272, 276-79 (2d Cir. 1981) ("where depictions of consumer test results or methodology are . . . significantly misleading . . . proof of diversion of sales is not required for an injunction to issue"); *American Home Prod.*, 577 F.2d at 167-69 (district court properly relied on survey results in deciding product superiority claim).

When an advertising claim is literally false, however, most courts will presume its materiality. *See* Alpo Petfoods, Inc. v. Ralston Purina Co., 720 F. Supp. 194, 214 (D.D.C. 1989) ("Since this court has found that Ralston's CHD claims are actually false, their materiality thus may be presumed."); *Energy Four, Inc.*, 765 F. Supp. at 731 ("actually false claims are presumed material") (citing PPX Enterprises v. Audiofidelity Enterprises, 818 F.2d 266, 272 (2d Cir. 1987)). In these instances, "[r]elief can be granted without reference to the reaction of consumers." *Id.* at 731.

The same is true when courts deal with *comparative* advertising, since, by definition, the advertisement specifically targets the plaintiff's trademark. *See Energy Four, Inc.*, 765 F. Supp. at 734 ("When an advertisement makes a misleading comparison to a specifically identified competing product, the value of the competing product is necessarily diminished in the mind of the consumer and irreparable injury may be presumed.").

[130] U.S. Healthcare, Inc. v. Blue Cross of Greater Philadelphia, 898 F.2d 914, 922 (3d Cir. 1990). *See, e.g., Energy Four, Inc.*, 765 F. Supp. at 730 n.1 ("Neither party disputes that the allegedly false and misleading representations were made in the realm of interstate commerce.").

[131] *U.S. Healthcare*, 898 F.2d at 922-23.

C. *Injunctive Relief: The Mainstay*

Once a plaintiff shows that a comparative scientific establishment claim is false, some form of injunctive relief should be available. Of course, a plaintiff must first demonstrate that it may suffer irreparable injury if the erroneous or misleading advertisement is allowed to persist.[132] With a false comparative scientific establishment claim, however, irreparable injury will be presumed[133] because "[a] misleading comparison to a specific competing product necessarily diminishes that product's value in the minds of the consumer."[134]

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[132] To recover damages under the Lanham Act, the plaintiff must show that it has actually lost sales as a result of the offending advertisement. But to obtain injunctive relief, the plaintiff need only show the likelihood of that eventuality. *See Coca-Cola*, 690 F.2d at 316; Upjohn Co. v. Riahom Corp., 641 F. Supp. 1209, 1225 (D. Del. 1986); Skil v. Rockwell Int'l Corp., 375 F. Supp. 777, 783 (N.D. Ill. 1974) ("In order to recover *damages* under section 43(a) [of the Lanham Act], plaintiff must establish that the buying public was actually deceived; in order to obtain *equitable relief*, only a likelihood of deception need be shown.") (citations omitted) (emphasis in original). This is not to say that injunctive relief may be granted on speculation that a competitor's false advertisement could affect sales. Thus, courts have emphasized that, while lost sales need not be shown to obtain equitable relief, a mere subjective belief of injury is insufficient. *Coca-Cola*, 690 F.2d at 316.

[133] *See* McNeilab, Inc. v. American Home Products Corp., 848 F.2d 34, 38 (2d Cir. 1988) (when a case involves a false comparative advertising claim, the trial court may presume irreparable injury "from a finding of false or misleading advertising"). *Compare Coca-Cola*, 690 F.2d at 316 (holding that the likelihood of injury and causation will not be presumed because the case did not involve false or misleading *comparative* advertising).

[134] *McNeilab*, 848 F.2d at 38. The court reasoned: "A misleading comparison to a specific competing product necessarily diminishes that product's value in the minds of the consumer. By falsely implying that Advil is as safe as Tylenol in all respects, AHP deprived McNeil of a legitimate competitive advantage and reduced consumers' incentive to select Tylenol rather than Advil. . . . In that context . . . irreparable harm will be presumed." *Id.* (citations omitted). Another court recently put the proposition in these terms:

> The expenditure by a competitor of substantial funds in an effort to deceive consumers and influence their purchasing decisions justifies the existence of a presumption that consumers are, in fact, being deceived. He who has attempted to deceive should not complain when required to bear the burden of rebutting a presumption that he has succeeded.

Hobart Corp. v. Welbilt Corp., 1989 U.S. Dist. LEXIS 14447, at *31 (E.D. Ohio Oct. 4, 1989) (citing U-Haul Int'l, Inc. v. Jartan, Inc., 793 F.2d 1034, 1041 (9th Cir. 1986)); *accord Energy Four*, 765 F. Supp. at 734 ("Given the intense and direct competition between the parties, it is clear that the court may presume that any false or misleading statements made by either party will injure the other."); E.R. Squibb & Sons, Inc. v. Stuart Pharmaceuticals, No. 90-1178, 1990 WL 159909, at * 18 (D.N.J. 1990) ("Irreparable harm is apparent in a multi-million dollar promotional campaign such as this between major pharmaceutical companies."); McNeil-P.P.C., Inc. v. Bristol-Myers Squibb Co., 755 F. Supp. 1206, 1210 (S.D.N.Y. 1990) ("Irreparable harm is generally presumed for Lanham Act violations because a false compari-

A trial court has broad discretion in framing the scope of the relief. In some cases, it may not be enough for the defendant to simply stop its advertising campaign. Rather, it may be necessary to require the defendant to take affirmative actions to minimize or eliminate any consumer confusion.[135] Affirmative steps may be warranted because the message from a false claim "remains in the public mind and can influence consumer decisions long after the newspaper is consigned to the trash bin."[136] Moreover, a

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son to a specific product reduces the consumers' incentive to purchase that product.") *aff'd.*, 938 F.2d 1544 (2d Cir. 1991).

135 *Upjohn*, 641 F. Supp. at 1226 (citations omitted).

136 *U-Haul Int'l*, 601 F. Supp. at 1144. In Linotype Co. v. Varityper, Inc., No. 89 CIV. 4747, 1989 WL 94338 (S.D.N.Y. Aug. 4, 1989), for example, the court ordered corrective advertising. The court reasoned:

> The relief ordered should be oriented toward eliminating the false nature of the offending advertisement, as well as the confusion it engenders in the minds of consumers. Corrective advertising may be ordered where appropriate.
>
> We believe that an adequate remedy here requires both an end to the circulation of the offending advertisement, and some form of corrective advertising.
>
> . . . .
>
> [I]n order to counteract the false impression that may have been placed by the ad in consumer's minds, Varityper shall publish a corrective advertisement. The corrective ad is to be placed, as soon as possible, in the same publications in which the offending ad appeared, for the same number of consecutive issues, and in the same size and frequency as that of the offending ad.

Id. at *3 (citations omitted). *Accord* Ames Publishing Co. v. Walker-Davis Publications, Inc., 372 F. Supp. 1, 15-16 (E.D. Pa. 1974) (ordering that the defendants "cause to be published and issued at their expense [a corrective notice] . . . to each person . . . to whom or which defendants have previously given . . . all or any part of defendants' [false advertising materials]"); *cf.* Paramount Pictures Corp. v. Worldwide Entertainment Corp., 195 U.S.P.Q. (BNA) 539, 543 (S.D.N.Y. 1977) (district court "has the power to order cure of publications"); Metro Mobile CTS, Inc. v. NewVector Communications, Inc., 643 F. Supp. 1289, 1296 (D. Ariz. 1986) (recognizing the authority "to have the court order [the defendant] to run corrective advertisements to cure the taint of its false or misleading advertisements"), rev'd, 803 F.2d 724 (9th Cir. 1986)(unreported), on remand, 661 F. Supp. 1504 (D. Ariz. 1987), aff'd, 892 F.2d 62 (9th Cir. 1989); Warner-Lambert Co. v. FTC, 562 F.2d 749, 761-62 (D.D.C. 1977), *cert. denied*, 435 U.S. 950 (1978) (after a false advertisement ceases, the message of the advertisement lives on and continues to harm the competition as well as the consuming public, which should not be misled to buy products on the basis of the false advertising).

For these reasons, many commentators have endorsed corrective advertising. *See* Pompeo, *supra* note 129, at 565 ("One injury is the lingering or residual effect that the message has on the consumer. . . . Furthermore, subsequent truthful ads which are not corrective in nature may serve to reinforce the deception by stimulating the false perception through continued exposure to the product or service.") (citations omitted); Note, *"Corrective Advertising" Orders of the Federal Trade Commission*, 85 HARV. L. REV. 477, 493-94 (1971) (corrective advertising counteracts the lingering effects of false advertisements).

simple injunction prohibiting further false claims may not serve to adequately deter false advertising.[137] Appropriate affirmative steps may include a recall of the offending advertisements,[138] an order prohibiting the defendant from filling orders obtained on the basis of the false claim,[139] and mandatory corrective advertising.[140]

In determining whether injunctive relief is appropriate, as well as the form it may take, courts have historically considered

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137 One court has persuasively observed, albeit in the context of an FTC enforcement action, that the mere prohibition of further false advertising is not enough to discourage false claims in the first instance:

> [F]or an advertiser who knowingly advertises falsely a simple cease and desist order provides no real deterrent. He has nothing to lose but attorneys' fees. He gets to use the deceptive advertisements until he is caught. . . . By the time the order has become final, the particular campaign has probably been squeezed dry, if not already discarded. In the meantime the seller has increased his market share and reaped handsome profits. The order to cease making the false claims takes none of this away from him. In short, "[a] cease and desist order which commands the respondent only to 'go, and sin no more' simply allows every violator a free bite at the apple."

Warner-Lambert, 562 F.2d at 761-62 n.60 (citation omitted).

138 *See, e.g., Upjohn Co.*, 641 F. Supp. at 1226-27 (on a preliminary injunction application, defendants ordered to, among other things, recall offending promotional materials, cancel pending orders for products, and "send a written notice to each of the customers . . . notifying them that the orders have been canceled because defendants are unable to supply the product.").

139 *See, e.g.*, CB Sports Inc. v. Gaechter-Haber & Assoc., 210 U.S.P.Q. (BNA) 597, 604 (D. Vt. 1981) (preliminary injunction directing party not to fill orders emanating from a false advertisement); Playskool, Inc. v. Product Development Group, Inc., 699 F. Supp. 1056, 1063 (E.D.N.Y. 1988) (preliminary injunction requiring defendants "to recall all of their product already sold and distributed which contains the [offensive] language"); Tree Tavern Products, Inc. v. Conagra, Inc., 640 F. Supp. 1263, 1273 (D. Del. 1986) (preliminary injunction requiring defendant "to recall and remove from distribution" offending articles).

140 Avis Rent a Car System, Inc. v. The Hertz Corp., 226 U.S.P.Q. (BNA) 95, 96 (E.D.N.Y 1985) (defendant ordered to publish corrective advertisements in same publications that carried the offensive advertisement; defendant required to state that its earlier ad was not true, that it was compelled to print retractions by court order, and that it was compelled to do so at its own expense), *rev'd on other grounds*, 782 F.2d 381 (2d Cir. 1986); *Ames Publishing*, 372 F. Supp. at 16 (defendant ordered to distribute a direct mailing of corrective information); *cf.* CB Fleet Co. v. Complete Packaging Corp., 739 F. Supp. 393, 399 (N.D. Ill. 1990) (preliminary injunction requiring defendants to "notify each person or entity to which they have already sold any of the goods in question. . . and immediately recall those goods from the purchasers . . . ."); Maybelline Co. v. Noxell Corp., 643 F. Supp. 294, 297-98 (E.D. Ark. 1986) (preliminary injunction requiring defendant to cease sale of offending product, "to send a letter to all to whom [the product] has been distributed directing them to withhold further sales . . . at this time," and to "advise the Court and opposing counsel [of] the steps which have been effectuated to carry out the terms of this provision. . . ."), *rev'd on other grounds*, 813 F.2d 901 (8th Cir. 1987).

the public interest. A Lanham Act case challenging a false scientific establishment claim unquestionably involves the public welfare. This is particularly the case when the false advertising claim — like a false safety or efficacy claim concerning a medication — jeopardizes the safety or well-being of consumers who may rely on it.[141]

IV. SCIENTIFIC ESTABLISHMENT CLAIMS UNDER THE LANHAM ACT

A. The Lanham Act Establishment Claim

The concept of an "establishment claim" first entered Lanham Act jurisprudence in 1986 with *Thompson Medical Co. v. Ciba-Geigy*.[142] The court defined an establishment claim as one that "represents that there is scientific evidence which establishes the truth of the statement."[143] To be sure, there were some intellectual precursors of that development. Courts had previously held, for example, that the Lanham Act prohibits not only false statements about products, but also false statements about the *scientific data* underlying product claims.[144]

Courts have not, however, entirely embraced the FTC's jurisprudence governing scientific establishment claims. Courts have, for example, split on whether "prior substantiation" of the claim is required under section 43(a). At least one court has held that an advertising claim, made without pre-existing data to support the claim, is a false claim within the meaning of section 43(a).[145] Most courts, on the other hand, have held that a plaintiff must prove that the claim itself is false and may not prevail by simply showing that the defendant cannot substantiate its

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[141] *See, e.g.*, Energy Four, Inc. v. Dornier Medical Systems, Inc., 765 F. Supp. 724, 736 (N.D. Ga. 1991) (court orders both parties to engage in massive corrective advertising campaigns to correct false statements implicating safety and efficacy of medical devices); E.R. Squibb & Sons, Inc. v. Stuart Pharmaceuticals, No. 90-1178, 1990 WL 159909, at *18 (D.N.J. Oct. 16, 1990) ("The public interest favors the issuance of an injunction when the health of a large percentage of the population is at stake.").

[142] 643 F. Supp. 1190 (S.D.N.Y. 1986). This was a Lanham Act case involving issues similar to those in a concurrent FTC action, Thompson Medical Co. v. FTC, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). In *Ciba-Geigy*, the court applied the "establishment claim" concept developed under the FTCA.

[143] *Ciba-Geigy*, 643 F. Supp. at 1196.

[144] *See* Vidal Sassoon, Inc. v. Bristol-Myers Co., 661 F.2d 272, 277 (2d Cir. 1981) (Lanham Act embraces misrepresentations regarding the methods and results of tests).

[145] Johnson & Johnson v. Carter-Wallace, Inc., 484 F. Supp. 975, 991-92 (D.N.J. 1979).

claim.[146]

The distinction is an important one and was dispositive in *Energy Four, Inc. v. Dornier Medical Systems, Inc.*[147] In that case, Dornier Medical Systems (Dornier) challenged Energy Four's performance claims concerning a competing medical device. Dornier showed that Energy Four did not have sufficient evidence to establish the truth of its claims, but the court concluded that Dornier could not prevail on that showing alone. The court held: "Energy Four's claims regarding [product performance] may not have been fully substantiated . . . but Dornier failed to show that these claims were actually false. . . . [Likewise] Energy Four did not carry its burden of showing [Dornier's] claims substantially likely to be proven false."[148]

The "prior substantiation" question arises only in the context of *non-establishment claims* (*i.e.*, when the advertiser makes an objective representation about its product but does not expressly represent that it has been proven or that any particular evidence supports the representation). In these instances, the plaintiff must do more than show that the defendant lacks the evidence to support its claim. Rather, the plaintiff must actually prove that the claim is false.[149] With an establishment claim, the advertiser asserts not only that its product claim is true, but also that it has the scientific evidence to prove it. If either proposition is false (*i.e.*, the product is not superior or the advertiser does not have the evidence to prove its claim), the advertisement is false.

FTCA and Lanham Act jurisprudence coincide on the critical importance of substantiation in their treatment of establishment claims. The existence of substantiation assumes a talismanic role because establishment claims can be measured against a single criterion: whether the advertiser actually has the claimed substantiation. Plaintiffs challenging establishment claims in a section 43(a) action should prevail on the merits if they can simply show that the advertiser's substantiation, if any, falls short of its claim.[150]

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146 *See, e.g.*, U-Haul Int'l v. Jartran, Inc., 522 F. Supp. 1238, 1249 (D. Ariz. 1981) (plaintiff must show that significant numbers of the buying public are deceived).

147 765 F. Supp. 724 (N.D. Ga. 1991).

148 *Id.* at 733.

149 *Id.* at 732 (citing Procter & Gamble Co. v. Chesebrough-Ponds, Inc., 747 F.2d 114, 119 (7th Cir. 1984)).

150 *See Energy Four*, 765 F. Supp. at 731-32.

B. *Truth Requires Good Science, Not Good Faith*

An establishment claim is either true or false. The advertiser either has the claimed substantiation or it does not. In some cases, however, the courts have declined to address the scientific issues and have instead focused on questions of intent or good faith.[151] This reluctance to decide the scientific issues may be understandable because those issues often lie beyond a court's expertise. But the task is required by the Lanham Act and is essential to serve its public policy objectives.

In *Proctor & Gamble Co. v. Chesebrough-Pond's Inc.*,[152] the Second Circuit correctly addressed the court's role in evaluating scientific evidence underlying product superiority claims. In that case, two leading manufacturers of hand and body lotions challenged each other's comparative advertising. Proctor & Gamble (P&G) claimed not only that its lotion was "better" than the lotion marketed by Chesebrough-Pond's Inc. (Chesebrough), but that dermatologists had proven it in clinical tests.[153] Chesebrough asserted that its lotion was as effective as any leading brand.[154] Both parties sought preliminary injunctive relief.

In extensive hearings, Chesebrough argued that P&G's tests reflected highly questionable data manipulated to reach a desired conclusion. Conversely, P&G attacked Chesebrough's studies as

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151 These courts may be satisfied, for example, by evidence of scientific tests, apparently conducted in good faith, that arguably support the advertising claim. Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 735 F. Supp. 597 (D. Del. 1989), *aff'd*, 902 F.2d 222, 228 n.7 (3d Cir. 1990), is a good example. In that case, Richardson-Vicks (Vicks) asserted that its cough syrup medication, Pediatric 44, was superior to the cough medicine marketed by Sandoz Pharmaceuticals (Sandoz) because Pediatric 44 starts to work the instant it is swallowed. Sandoz claimed that "the representations about the instant action of the product are false" (*i.e.*, not "scientifically true") within the meaning of the Lanham Act. *Sandoz*, 902 F.2d at 223.

The district court found that Vicks performed "various tests" to support its claim and recognized that the truth of the claim depended on those tests. *See Richard-Vicks*, 735 F. Supp. at 600 ("Vicks' claim . . . depends for its truthfulness on Vicks' assertions regarding the effectiveness of Pediatric 44's demulcents and the thickness of its inert syrup."). Rather than determine the "truthfulness" of Vicks's claim, based on the scientific evidence, however, the district court was instead content to find that Vicks's claim "could" be true. As the Third Circuit noted, the district court "first found that Vicks's consumer advertising claims were not literally false, because Vicks's test results indicated that the demulcents in Pediatric 44 *could* begin to work immediately." *Sandoz*, 902 F.2d at 225 (emphasis added).

152 747 F.2d 114 (2d Cir. 1984).

153 *Id.* at 116.

154 *Id.*

too narrow in scope, poorly designed, sloppily executed, and improperly analyzed.

The district court noted that each party's tests suffered from serious flaws. The judge concluded that he could not determine the veracity of either company's claim and, therefore, denied any preliminary injunctive relief to either party.[155] In the course of his opinion, the judge suggested that the outcome of these controversies should turn on questions of the parties' good faith.[156] In addition, the judge suggested that disputes of this nature did not really belong in the federal courts.

The Second Circuit devoted the better part of its opinion to clarifying the law on these two points. The court emphasized that, while proof of bad faith is not required, proof of good faith would not immunize a defendant.[157] The circuit court also emphasized that a trial court must actually decide the scientific issues:

> Although the task of evaluating scientific product tests may be challenging and distasteful because of the technical and theoretical nature of the procedures involved and the intricate statistical analysis needed to derive qualitative inferences and conclusions from the data, the court is under just as much of a duty to consider and weigh such evidence as it is to analyze economic or scientific evidence in a complicated patent or antitrust case. That a district court, sitting as trier of the facts, must consider, analyze and weigh expert testimony regarding clinical testing standards, procedures and results, has long been recognized.[158]

The Second Circuit noted that, while a party's bad faith could support an inference of bad science, a party's good faith does not mean that it has necessarily produced good science. Consequently, proof of good faith would not validate poor product tests or immunize a manufacturer from false advertising claims.[159] Thus, Chesebrough could have prevailed simply by showing that P&G did not have the evidence that it claimed to have to establish the superiority of its lotion. As the Second Circuit noted:

> Chesebrough could obtain an injunction against P&G . . . by

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155 *Id.* at 118.

156 *See id.* at 119 (noting that the district court found the challenged claims to be "*not obviously false*," and based on tests conducted in "*apparent good faith*") (emphasis in original).

157 *Id.* at 119.

158 *Id.* at 120 (citations omitted).

159 *Id.*

> establishing that the latter's advertising claim of test-proven superiority was false. To prove such falsity Chesebrough assumed the burden of showing that *the tests referred to by P&G were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited.*[160]

In sum, when an advertiser asserts that a scientific test establishes its claim, courts must decide whether the scientific test actually establishes the claim. To resolve that question, courts must, in the final analysis, focus on the scientific evidence, not the advertiser's state of mind.

C. Common Fact Patterns

In cases involving scientific establishment claims, there are a few recurring fact patterns. The cases run the gamut from establishment claims with no scientific substantiation to claims supported by arguably good science — science conducted (and portrayed) in accordance with good scientific practices. The latter present the most difficult challenges to resolve.

1. No Real Science

The easiest case to resolve is one in which the defendant has made establishment claims with no real scientific evidence to support them. In *Thompson Medical Co. v. Ciba-Geigy Corp.*,[161] Thompson Medical Company (Thompson) claimed that studies demonstrated the superiority of Dexatrim over other weight-loss medications. After reviewing the studies cited by Thompson to support its establishment claim, the court found them fatally flawed and concluded that no credible study supported Thompson's claim. The court enjoined further advertising until the claim could be substantiated with valid clinical evidence.

Similarly, in *Upjohn Co. v. Riahom Corp.*,[162] Riahom claimed that the safety of its product had been clinically proven. In fact, the evidence showed that Riahom had performed minimal safety testing, far less than the FDA or any reasonable scientist would require. The court went so far as to charge the defendants' with "thumbing their noses at United States drug regulations."[163] The court wrote:

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160 *Id.* (emphasis added).
161 643 F. Supp. 1190 (S.D.N.Y. 1986).
162 641 F. Supp. 1209 (D. Del. 1986).
163 *Id.* at 1225.

> American consumers who see a product claiming that clinical tests have shown it safe for use expect that the product has gone through extensive and rigorous testing by the manufacturer, the government or both before its general sale. [Riahom's] minimal testing of [the product] hardly meets these expectations. A consumer's decision to buy [the product] might be affected if he or she knew that the safety tests involved only 59 subjects. . . . The Court concludes that [Riahom's] claim that clinical tests have shown the safety of [the product] is a deceptive statement covered by the Lanham Act.[164]

Ciba-Geigy and *Upjohn* were easy cases to resolve because the advertisers had no credible scientific evidence to support their claims. Another relatively easy type of false claim to identify entails the clear abuse of good science.

2. The Abuse of Good Science

Sometimes an advertiser will intentionally distort the findings of a valid study. In *P. Lorillard Co. v. FTC*,[165] Reader's Digest magazine had commissioned an independent laboratory study to compare the tar and nicotine content of competing cigarettes. The magazine reported that the results of its independent study showed no significant difference between the competing brands.[166] A table listing the results, designed to demonstrate practically no difference between the brands, showed that "Old Gold" manufactured by P. Lorillard Co. (Lorillard) enjoyed an insignificant advantage.[167]

Despite the express finding of the laboratory tests, and the entire thrust of the article, Lorillard proceeded to exploit them in its advertising. It claimed that the Reader's Digest experiments had found that Old Gold cigarettes contained the lowest amounts of nicotine, irritating tars and resins, as though a substantial difference had been found. In short, Lorillard acted as if it had "re-

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164 *Id.* at 1224.

165 186 F.2d 52 (4th Cir. 1950).

166 *Id.* at 57. The article concluded that the smoker "need no longer worry as to which cigarette can most effectively nail down his coffin. For one nail is just about as good as another." *Id.*

167 *Id.* As the court noted, "[t]he table referred to in the article was inserted for the express purpose of showing the insignificance of the difference in the nicotine and tar content of the smoke from the various brands of cigarettes. It appears therefrom that the Old Gold cigarettes examined in the test contained less nicotine, tars and resins than the others examined, although the difference . . . was so small as to be entirely insignificant and utterly without meaning so far as effect upon the smoker is concerned." *Id.*

ceived a citation for public service instead of a castigation from the Reader's Digest."[168]

In response to the FTC's complaint, Lorillard argued that it was truthfully relating an actual finding reported in the Reader's Digest article. The court rejected Lorillard's argument, reasoning that an advertiser could not cause the reader to believe the exact opposite of the author's intended conclusion. The court wrote:

> The fault with this advertising was not that it did not print all that the Reader's Digest article said, but that it printed a small part thereof in such a way as to create an entirely false and misleading impression, not only as to what was said in the article, but also as to the quality of the company's cigarettes. . . . To tell less than the whole truth is a well known method of deception; and he who deceives by resorting to such method cannot excuse the deception by relying upon the truthfulness per se of the partial truth by which it has been accomplished.[169]

Thus, in *Lorillard*, the advertiser distorted good science. Courts should have little difficulty in detecting and interdicting this type of false establishment claim.

3. Obsolete Scientific Literature

Sometimes an advertiser may rely on obsolete scientific literature to support a claim. Even if that literature by its own terms supports the advertiser's claim, that claim may be challenged under the Lanham Act. If the gist of the advertisement is not true in light of recent scientific evidence, the advertiser should not be permitted to exploit outdated information to garner an unfair competitive advantage.

In *E.R. Squibb & Sons, Inc. v. Stuart Pharmaceuticals*,[170] Stuart Pharmaceuticals (Stuart) claimed that its blood pressure medication was safer than a competing medication sold by E.R. Squibb & Sons, Inc. (Squibb). Specifically, Stuart suggested that patients taking its drug would experience fewer rashes and taste disturbances. To support those claims, Stuart cited to statements in the current *Physicians Desk Reference* (*PDR*).

The court found that Stuart's citation to the *PDR* could not "establish" its comparative safety claims for two reasons. First,

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168 *Id.* at 57.

169 *Id.* at 58.

170 No. 90-1178, 1990 WL 159909 (D.N.J. Oct. 16, 1990).

the *PDR* itself relied on outdated scientific literature. Even though Stuart did not misrepresent the *PDR* information, the claims were false because the *PDR* itself relied on outdated scientific literature.[171] Consequently, Stuart could not hide behind the *PDR*'s inaccuracy.[172] Second, the court found that Stuart had unfairly disregarded more current scientific information, including Stuart's own studies suggesting that its product posed a greater risk of serious side effects.[173]

Because scientific knowledge is constantly evolving, today's "truth" depends on today's scientific information. Just as lawyers may not rely on overruled authorities to support a legal position, an advertiser may not rely on outdated scientific studies to support an advertising claim. If an advertiser attempts to do so, a court should find that its establishment claim is false within the meaning of the Lanham Act.

4. Totally Unreliable Science

In some instances, an advertiser may conduct tests and accurately report their results. The tests may have been performed so badly, however, as to be totally invalid. In these instances, the tests cannot establish the advertising claims.

In *Alpo Petfoods, Inc. v. Ralston Purina Co.*,[174] Ralston Purina

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171 As the court noted, "both parties' experts agree[d] that the claims that Squibb's product caused rashes and taste disturbances were outdated." *Id.* at *14.

172 The court held:

> Both sides agree that the comparison about rash and taste disturbance is outdated. . . . As noted in court by counsel for Squibb, Stuart had in its possession an article written by doctors for [Stuart] which stated that, "although early clinical experience with [these medications] indicate a troublesome side effect profile, it is now recognized that used appropriately they are generally well tolerated." [Stuart] chose to hide behind the *PDR*. The court finds this unsatisfactory.

Id. at *18.

173 To support its efficacy claims, Stuart cited a study that it had commissioned. But Stuart chose to ignore unfavorable data from that study when it proceeded to make its comparative safety claims:

> [T]he court considers it a material omission to fail to mention the adverse side effects of [Stuart's medication]. Indeed, the [study] found that [Stuart's medication] produced a side effect of cough four times more often than [Squibb's medication] and both drugs produced headache. The revised ad claims that [Stuart's medication] has a low incidence of side effects. It is false for Stuart to omit the information it had from the [study] about [these] side effects while presenting the negative side effects information about [Squibb's medication].

Id.

174 720 F. Supp. 194, 202 (D.D.C. 1989), *aff'd in part, rev'd in part on other grounds*, 913 F.2d 958 (D.C. Cir. 1990).

Company (Ralston) claimed that its dog food reduced or eliminated canine hip dysplasia (CHD) based on its in-house scientific research. Alpo Petfoods Inc. (Alpo) challenged Ralston's advertising claim. The district court heard weeks of conflicting expert testimony on the scientific basis for Ralston's CHD-related advertising. The court appropriately defined the standard governing litigation:

> A product claim is false under the Lanham Act if the representation cites tests or other authority that does not substantiate the claim made; that is if the false substantiation is part of the representation. A representation purportedly supported by clinical research may be deemed false if it is shown that *the tests referred to were not sufficiently reliable to permit a reasonable conclusion that the research established the claim made.*[175]

The court carefully scrutinized the scientific evidence that Ralston cited to support its claim. The court found that Ralston had, among other things, improperly combined unrelated data to attain statistical significance, ignored warnings from its researchers concerning the validity of its data, discarded inconsistent results, failed to properly control variables, failed to properly select test animals, and failed to establish accurate methods of testing for CHD. Consequently, the court found that Ralston's study was totally invalid and could not establish its claims.[176]

In cases of this sort, like the other types we have previously examined, courts should have little difficulty in determining that the scientific evidence cited to support an establishment claim does not, in fact, establish the claim. The most difficult cases, however, are discussed next. These involve instances in which the advertiser has

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[175] *Id.* at 213 (emphasis added) (citations omitted). *Accord* McNeil-P.P.C., Inc. v. Bristol-Myers Squibb Co., 755 F. Supp. 1206, 1211 (S.D.N.Y. 1990) ("A claim of test proven superiority may be deemed false if it is shown that the clinical research purportedly supporting the representation was not sufficiently reliable to permit the reasonable conclusion that the research established the claim made."), *aff'd.*, 938 F.2d 1544 (2d Cir. 1991).

[176] The court wrote:

> This court finds that inadequacies in the design and execution of Ralston's research were so substantial that the data gleaned from the tests are not valid. This finding is based on the court's evaluation of the design of the CHD research, the methods used in conducting the trials, the inability to explain how the anion gap formula affects hip joint formation, the objectivity and skill of the persons conducting the tests and their concerns that the research did not adequately support the claims made by Ralston.

Alpo Pet Foods, 720 F. Supp. at 206.

good science to support its claim, but the scientific evidence just may not suffice to *establish* the claim.

5. Good Science Short of the Mark

The most difficult cases to resolve are those in which a good scientific effort produced good science, but the data may not suffice to establish the claim. In *American Home Products Corp. v. Abbott Laboratories*,[177] Abbott Laboratories (Abbott) claimed that, "in a major consumer preference test," its product was preferred "more than 2 to 1."[178] The court found that Abbott's advertising correctly reported the results of the study and that the study was "colorably" valid.[179] But the court held that American Home Products Corporation (American) could still prevail if it showed, by more reliable data, that Abbott's claims were false. The court wrote:

> Evidence of tests that are both methodologically superior and practical would be highly relevant. . . . *[A defendant may not] escape liability for comparative claims merely because its test methodology was sufficiently rigorous to escape a judgment of methodological invalidity as a matter of law.* A plaintiff may well meet its burden of proving a Lanham Act violation by establishing, on the basis of more reliable test results, that the claim was in fact false or misleading.[180]

Thus, a defendant may not prevail by simply showing that its test is colorably valid and that its advertisement accurately reported the results. The issue is whether the overall message of superiority is true. To make that determination, courts must consider the question in light of all the scientific evidence presented.

D. Evaluating the Science

There is no "bright-line" test to distinguish between good and bad science, valid and invalid conclusions, and studies that can and cannot establish a particular claim. Indeed, science itself recognizes no clear demarcation. The absence of any bright-line test, however, does not mean that a scientific judgment may be entirely subjective.

To evaluate claims based on scientific evidence, scientists consider several criteria. Courts should apply these criteria in

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177 522 F. Supp. 1035 (S.D.N.Y. 1981).
178 *Id.* at 1037.
179 *Id.* at 1038-39.
180 *Id.* at 1039 (emphasis added).

Lanham Act litigation. If an advertiser asserts that a particular study has established a claim, the courts should consider what evidence the scientific community would require before concluding that a similar claim has been established.[181]

The FDA follows this approach. Under FDA regulations, the substantiation must be such that "it can fairly and responsibly be concluded by [qualified] experts that the drug is safe and effective for [the advertised] uses."[182] Similarly, in evaluating substantiation of drug advertising claims, the FTC also "looks to what the scientific or medical community would require, as evidenced by such sources as FDA regulations, expert opinion and/or expert panel reports."[183] Consequently, the FTC's standards often coincide with those of the FDA. The FTC has noted that the FDA's standards for evaluating scientific studies cited in food and drug advertisements:

> [P]arallel well-established principles under the FTC's ad substantiation doctrine. Commission orders often require that advertisers possess "reliable and competent evidence" to substantiate their representations, and typically define such evidence as those tests, analyses, research, studies, or other evidence 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.[184]

In Lanham Act cases, courts have adopted many of the standards used by the FDA and the FTC to evaluate scientific studies. Although courts should always consider "all relevant circumstances,"[185] several tend to play a pivotal role in these cases.

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181 *See* Removatron Int'l Corp. v. FTC, 884 F.2d 1489, 1498 (1st Cir. 1989) (in evaluating an establishment claim, the FTC "determines what evidence would in fact establish such a claim in the relevant scientific community. It then compares the advertisers' substantiation evidence to that required by the scientific community to see if the claims have been established.") (citation omitted).

182 21 C.F.R. § 202.1(e)(4)(iii)(b) (1991).

183 *Comments Regarding Health Messages*, *supra* note 22, at 15 n.36 (citing In the Matter of Thompson Medical Co., Inc., 104 F.T.C. 648, 825-26 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987)).

184 *Comments Regarding Health Messages*, *supra* note 22, at 16-17 (citing In the Matter of Pharmtech Research, Inc., 103 F.T.C. 448, 459 (1984)).

185 Thompson Medical Co. v. Ciba-Geigy Corp., 643 F. Supp. 1197 (S.D.N.Y. 1986). The "relevant circumstances" may include "the state of the testing art, the existence and feasibility of superior procedures, the objectivity and skill of the person conducting the test, the accuracy of their reports, and the results of other pertinent tests." *Id.* (citing Proctor & Gamble Co. v. Chesebrough-Pond's Inc., 747 F.2d 114, 119 (2d Cir. 1984)).

1. Qualified Investigators

A study should be conducted by qualified investigators. Under FDA regulations, an advertising claim for a prescription drug must be based on studies conducted by "experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved. . . ."[186] In addition, the FTC has generally preferred that experts be "independent."[187]

Whether an investigator is qualified or sufficiently independent remains a fact-sensitive question. In evaluating expert witnesses, courts consider a variety of factors, including their "real-world" experience,[188] their familiarity with the relevant published literature,[189] whether they have published in the field,[190] are members of relevant professional societies,[191] and whether they consider themselves to be an expert in the field.[192] Failure to satisfy criteria similar to these undermined Ralston's claims in *Alpo Petfoods*.[193]

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186 21 C.F.R. § 202.1(4)(b)(3)(*b*) (1991).

187 For example, the FTC's experts agreed that "a [product's] efficacy should be tested in clinical trials conducted by independent investigators, for one investigator's commitment to the hypothesis being tested may influence his perceptions of a study's results." In the Matter of Schering Corp., No. 9232, slip op. at 36 (Initial Decision, Sept. 16, 1991).

188 *See* In re Air Crash Disaster At New Orleans, Louisiana, 795 F.2d 1230, 1234 (5th Cir. 1986) ("[T]he professional expert is now commonplace. That a person spends substantially all of his time consulting with attorneys and testifying is not a disqualification. But experts whose opinions are available to the highest bidder have no place testifying in a court of law, before a jury, and with the imprimatur of the trial judge's decision that he is an 'expert.' "); Hartke v. McKelway, 526 F. Supp. 97, 101 (D.D.C. 1981) (physician's "reading of literature and conferring with other physicians on the eve of trial did not qualify her to testify"), *aff'd*, 707 F.2d 1544 (D.C. Cir.), *cert. denied*, 464 U.S. 983 (1983).

189 Will v. Richardson-Merrell, Inc., 647 F. Supp. 544, 548 (S.D. Ga. 1986). *See also* Thompson v. Merrell Dow Pharmaceuticals, Inc., 229 N.J. Super. 230, 241, 551 A.2d 177, 183 (App. Div. 1988) (witness not qualified because his "expertise" in the field was "based solely on a few articles he had read in preparation for his testimony").

190 *See* Richardson by Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 826 (D.C. Cir. 1988) (expert not qualified because he "had neither performed his own studies nor published his criticisms of the studies performed by others").

191 *See* Smith v. Hobart Manufacturing Co., 185 F. Supp. 751, 756 (E.D. Pa. 1960) (expert not qualified in engineering because, among other things, he was not "a member of at least one organization or society dedicated to the improvement of that profession").

192 *See, e.g.*, Gates v. United States, 707 F.2d 1141, 1145 (10th Cir. 1983) (witness not qualified to render an opinion because he admitted that he was not qualified to render an opinion); *Thompson*, 229 N.J. Super. at 236, 551 A.2d at 181 (witness "acknowledged that he was not qualified to render an opinion. . . .").

193 The court noted:

> The objectivity and skill of those conducting the tests is also a factor

2. An Objective Methodology

The scientific method requires objectivity.[194] Consequently, the proponent of a study should be prepared to show that generally accepted scientific procedures were used to yield reliable results.[195] In *Alpo Petfoods*, Ralston's data lacked credibility because its investigator "used a test method which had not been used or approved for use by any experts or established research organizations."[196]

An objective methodology in a clinical trial of prescription drugs also requires a protocol defined *in advance* of the study.[197] A protocol insures that, as the test progresses, investigators will not make ad hoc adjustments to reach a desired outcome. The protocol should prescribe, in advance, how the test will be conducted and how the data will be analyzed. The latter is essential to avoid "data dredging" — looking through results without a predetermined plan until one finds data to support a claim.[198]

FDA regulations codify this principle. Under the regula-

> in the court's determination. Dr. Kealy, who conducted and supervised Ralston's CHD research, spent very little of his professional life in CHD research. None of the papers authored by Dr. Kealy, with the exception of Ralston's promotional research monograph, concern CHD. Only three relate to dogs: two concerning calcium metabolism and one on the evaluation of a dog's coat of hair. Additionally, Dr. Kealy, as an employee of Ralston, had a strong interest in seeing that the research conducted supported the anion gap theory, especially since a good portion of the research was performed while market planning for the formula was already underway.

Alpo Petfoods, Inc. v. Ralston Purina Co., 720 F. Supp. 144, 207-08 (D.D.C. 1989), *aff'd in part, rev'd in part*, 913 F.2d 958 (D.C. Cir. 1990), *modified*, 1991 WL 25793 (D.D.C. 1991).

194 *See* In the Matter of Pharmtech Research, Inc., 103 F.T.C. 448, 459 (1984); In the Matter of Porter & Dietsch, Inc., 90 F.T.C. 770, 868, 885 (1977), *aff'd sub nom.* Porter & Dietsch Inc. v. FTC, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980).

195 Of course, if a published study does not adequately describe its methodology, the study may not be adequately evaluated. In that instance, it may not provide much support, if any, to sustain a claim. *See* In the Matter of Schering Corp., No. 9232, slip op. at 49 (Initial Decision, Sept. 16, 1991) (declining to consider a particular study because "the description of its design, implementation and results is so brief that one cannot assume its validity and reliability").

196 *Alpo Petfoods*, 720 F. Supp. at 207.

197 In *Schering*, the experts agreed that a pre-defined protocol represents one element of a "well-conducted and controlled clinical trial." *Shering*, No. 9232, slip op. at 35. Further, "[a] pre-study protocol should be devised which sets forth how the research is to be implemented and analyzed, including how subjects are to be randomized into treatment groups, and what statistical techniques are to be employed." *Id.* at 35.

198 *See* In the Matter of Thompson Medical Co., 104 F.T.C. at 825-28.

tions, an advertisement may be false if it "[u]ses statistical analyses and techniques on a *retrospective basis* to discover and cite findings not soundly supported by the study. . . ."[199] Thus, to satisfy FDA standards, statistical analyses should be defined in advance of the test.[200] Retrospective statistical manipulations clearly discredited Ralston's claims in *Alpo Petfoods*.[201]

In *E.R. Squibb & Sons, Inc. v. Stuart Pharmaceuticals*,[202] the court addressed the significance of a scientific protocol:

> A protocol is a plan to be carried out to answer the question posed by the study. It is usually drawn up by the investigator and the other people who are collaborating in planning the clinical trial. It is a blueprint or a set of ground rules which describe the goal of the trial and contains a complete description of the plans for the study.
>
> Adherence to a protocol protects against post-study questions that may arise as to the goals, motives or plans of the study or allegations that the investigator changed his analysis in response to various findings in the data.[203]

To be sure, not every deviation from a protocol will be fatal. In *Squibb*, the court found that Stuart actually intended to perform the study in a particular manner but simply failed to formally revise its protocol before initiating the study. Hence, the court found that Stuart's deviations from the original protocol were "insufficient to establish that the test results were false [and] did not render the study results illegitimate."[204]

On the other hand, intentional deviations from a protocol may demolish the integrity of a study. In *Alpo Petfoods*, the court found that, to reach desired conclusions, Ralston repeatedly deviated from its protocol.[205] Moreover, in presenting the conclusions of its laboratory tests, Ralston improperly omitted references to one finding

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199 21 C.F.R. § 202.1(e)(7)(iii) (1991) (emphasis added).

200 FDA regulations also provide that an advertising claim is false if the analysis underlying the claim:

> Uses 'statistics' on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such 'statistics' are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

21 C.F.R. § 202.1(e)(6)(xiv) (1991).

201 *Alpo Pet Foods*, 720 F. Supp. at 208.

202 No. 90-1178, 1990 WL 159909 (D.N.J. Oct. 16, 1990).

203 *Id.* at *6.

204 *Id.* at * 7.

205 *Alpo Petfoods*, 720 F. Supp. at 209.

that totally discredited the basic premise of its scientific theory.[206] The court, therefore, appropriately held that Ralston's tests could not establish its scientific claims.

3. A Sound Methodology

FDA regulations require that advertising claims for drugs be supported by "adequate and well-controlled clinical investigations."[207] FTC decisional law similarly requires "well-conducted and controlled clinical trials."[208] Thus, under FDA regulations, an advertisement will be considered false or misleading if its claims are based on a study with inadequate design, scope or conduct, such that the study cannot support the claims.[209]

There is no single definition of an "adequate and well-controlled clinical investigation." Several principles, however, are uniformly recognized. In addition to a pre-defined protocol, a process known as "double blinding" should be implemented. With this process, neither the investigator nor the subject knows whether the latter is receiving the active drug or a placebo. When any form of "subjective measurement" is made (for example, pain reduction), double blinding is critical because perceptions may be affected by knowledge of a drug's intended effects.[210]

When a placebo is used, the placebo should have the same appearance as the active ingredient.[211] Note, however, that a placebo may not be required in certain direct drug-to-drug comparative studies.[212]

Next, a sound methodology utilizes "randomization." With randomization, it is equally probable that subjects will be as-

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206 *Id.* at 204.

207 *See, e.g.*, 21 C.F.R. § 202.1(e)(4)(iii)(b) (1991) (there must be "substantial evidence of safety and effectiveness, consisting of adequate and well-controlled investigations, including clinical investigations").

208 In the Matter of Schering Corp., No. 9232, slip op. at 35 (Initial Decision, Sept. 16, 1991).

209 21 C.F.R. § 202.1(e)(7)(i) (1991).

210 *See Schering*, No. 9232, slip op. at 35 ("The product should be tested against a placebo, which controls for the effect which test subjects often experience simply because they are being treated. A placebo helps control for the subjective reactions of the subject and subjective input from the investigator.").

211 *Id.* at 36.

212 *See* E.R. Squibb & Sons, Inc. v. Stuart Pharmaceuticals, No. 90-1178, 1990 WL 159909 (D.N.J. Oct. 16, 1990); *see also* McNeil-P.P.C., Inc. v. Bristol-Myers Squibb Co., 755 F. Supp. 1206, 1214 (S.D.N.Y. 1990) (describing the "cross-over study" in which each subject receives one drug, then the other, and effectively serves "as his own control").

signed to either the treatment or the control group.[213] Randomization is designed to eliminate assignment bias, a prejudice that might occur if the investigators were free to assign particular subjects to particular groups.[214]

4. Consistency with Independent Data

A reasonable scientist should be less likely to conclude that a single new study establishes a proposition when the study conflicts with prevailing authority. Courts have recognized that what may be said to be "scientifically known" resides in "the totality of the published scientific literature on the subject . . . which collectively represents the sum of all that can be said to be scientifically 'known' of the matter at present. . . . [T]he 'literature' is to scientists both the ultimate authority as to and the most respected repository of scientific knowledge."[215]

In *Alpo Petfoods*, the court, considering the weight of independent scientific authority, noted that the overwhelming weight of credible scientific authority contradicted Ralston's claims.[216] The court held that representations contradicted by prevailing authority may be false on their face and actionable under section 43(a) of the Lanham Act.[217]

In this regard, publicly available data should be more credible than solely proprietary data because "the data will be subject to the review and criticism of the scientific community. . . ."[218] As the FTC has explained: "[B]ecause of the peer review and criticism that publicly available research will face, such research is likely to be more rigorously tested and carefully performed than

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213 *Schering*, No. 9232, slip op. at 36.

214 *Id.*

215 Richardson by Richardson v. Richardson-Merrell, Inc., 649 F. Supp. 799, 802 (D.D.C. 1986), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989).

216 Alpo Petfoods, Inc. v. Ralston Purina Co., 720 F. Supp. 194, 209 (D.D.C. 1989), *aff'd in part*, 913 F.2d 958 (D.C. Cir. 1990).

217 *Id.* at 213. *See also* McNeil-P.P.C., Inc. v. Bristol-Myers Squibb Co., 775 F. Supp. 1206, 1211 (S.D.N.Y. 1990); *Schering*, No. 9232, slip op. at 47 ("Although analysis of the individual merits or faults of the studies is of paramount importance, their results must be viewed in light of the fact that, at the time Schering disseminated its Fibre Trim advertising, other evidence suggested that fiber's ability to cause weight loss was questionable."); *id.* at 71 ("[R]eputable scientific bodies, both before and after dissemination of the advertisements, were skeptical about the efficacy of fiber as a weight loss aid. The FDA's 1982 proposal to establish a weight loss monograph stated that the value of bulk producers like Fibre Trim had not been established.").

218 *Comments Regarding Health Messages*, *supra* note 22, at 23.

in-house proprietary research."[219]

If scientific literature conflicts with an advertiser's study, the advertiser's independent claim may very well be false or misleading. At the very least, however, "it may be necessary for a manufacturer to disclose the existence of contrary evidence in order to ensure that consumers are not misled."[220]

5. The Size or Power of the Study

The size or power of a scientific study is important. The larger the study, all other things being equal, the more likely it is that its results will be clinically significant. Under FDA regulations, an advertisement may be false if it "[p]resents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does."[221] Yet, when data are limited, the advertising claim may still be allowed if the claim is appropriately qualified so that the advertisement does not imply to consumers that a higher level of substantiation exists.[222]

6. Replication

In general, the FDA calls for two or more studies to support a claim.[223] The FDA's requirement codifies the scientific princi-

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219 *Id.*; *see also Schering*, No. 9232, slip op. at 36 ("Peer review and publication in a reputable scientific journal validates a study's worth."). In many contexts, courts have recognized the value of peer review. *See* Ellis v. Int'l Playtex, Inc., 745 F.2d 292, 302 (4th Cir. 1984). *See also* National Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 160-61 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978) (administrative law judge correctly relied on studies that "were conducted using scientific methodologies, were performed by competent and highly regarded investigators, have been reported in recognized scientific journals after peer review, and have been generally accepted by experts in the field and by the scientific community"); Perry v. United States, 755 F.2d at 888, 892 (11th Cir. 1985) (expert's opinion not credible because, among other reasons, the opinion lacked peer review); Wisconsin v. Weinberger, 578 F. Supp. 1327, 1345 n.15 (W.D. Wis.), *modified*, 582 F. Supp. 1489 (W.D. Wis.), *rev'd*, 745 F.2d 412 (7th Cir. 1984) (court relied extensively on peer-reviewed studies, noting that "[a]rticles published in peer review journals are screened in advance of publication by other[s] in the same fields"); Kubs v. United States, 537 F. Supp. 560, 562 (E.D. Wis. 1982) (a scientific study has "little probative value" if it was never "subject to extensive peer review prior to publication"); Zeck v. United States, 559 F. Supp. 1345, 1349 n.3 (D.S.D. 1983) (in a peer-reviewed study, "[t]he conclusions and methods used to reach the conclusion[s] are held to exacting scientific standards"), *aff'd*, 720 F.2d 534 (8th Cir. 1984).

220 *Comments Regarding Health Messages*, *supra* note 22, at 14 n.31 (citation omitted).

221 21 C.F.R. § 202.1(e)(6)(v) (1991).

222 *Comments Regarding Health Messages*, *supra* note 22, at 13-14.

223 *See* 21 C.F.R. § 202.1(e)(4)(iii)(b) (1991) (calling for "adequate and well-con-

ple of replication, one that has been judicially recognized.[224] Ultimately, the principle of replication rests on an elementary principle of logic: if an apparent drug effect reflected in the first study is real, it will happen again; if it is not real, it will not happen again, and investigators may conclude that the initial findings are not to be taken at face value.

7. Statistical and Clinical Significance

To support an efficacy claim, a clinical study must show statistically significant results.[225] Statistically significant results suggest that the observed differences in effects derive from the treatment.[226]

A finding of statistical significance, however, does not imply "clinical significance" (*i.e.*, that the perceived difference is relevant to the use of a medication for treatment). In *The Matter of Schering Corp.*,[227] Schering relied on studies showing a "statistically significant" difference in weight loss due to the use of Fibre Trim. The ALJ concluded, however, that the results of the study were not "clinically significant" and, therefore, could not support Schering's claims.[228]

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trolled investigations"). The FTC has also indicated that "[c]onfirmation by independent research is . . . desirable." *Schering*, No. 9232, slip op. at 36.

224 *See, e.g.*, Gulf South Insulation v. United States Consumer Prod. Safety Comm'n, 701 F.2d 1137, 1146 (5th Cir. 1983) ("it is not good science to rely on a single experiment"); Wisconsin v. Weinberger, 578 F. Supp. 1327, 1349 (W.D. Wis.) (expert "noted the need for subsequent independent replication"), *modified*, 582 F. Supp. 1489 (W.D. Wis.), *rev'd on other grounds*, 745 F.2d 412 (7th Cir. 1984); Forsham v. Califano, 587 F.2d 1128, 1137 (D.C. Cir. 1978) ("reliability usually accorded to scientific studies [through] replication"), *aff'd sub nom.* Forsham v. Harris, 445 U.S. 169 (1980); In re "Agent Orange" Product Liability Litigation, 611 F. Supp. 1267, 1274 (E.D.N.Y. 1985) (studies relied on by the plaintiff's experts were unreliable because "[t]hese . . . studies have not been replicated by other investigators"), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom.* Lombardi v. Dow Chemical Co., 487 U.S. 1234 (1988) (studies relied on by the plaintiffs' experts were unreliable because "[t]hese . . . studies have not been replicated by other investigators").

225 *Cf.* 21 C.F.R. ¶ 202.1(e)(6)(xiv) (advertisement false if it erroneously suggests statistical significance). The conventional test of statistical significance requires a "p value" equal to or less than .05. This implies a result whose likelihood of occurrence by chance is less than five percent, or five times in one hundred occurrences. A "p value" greater than .05 is generally not accepted as an indication of an actual difference between placebo and control group. *See Schering*, No. 9232, slip op. at 37.

226 *Id.*

227 *Id.*

228 The ALJ observed:

> [S]tatistical significance alone does not validate a study, for the question remains: was the observed difference clinically significant or "clinically trivial." With respect to weight loss studies, some experts

8. Claims Based on Consensus and Published Literature

Sometimes an advertisement may expressly assert that a consensus of opinion supports a claim. In these instances, the consensus must exist.[229] The advertiser should possess the scientific literature necessary to establish the consensus.

FDA regulations recognize a similar principle. An advertising claim may be false if it "[c]ontains information from published or unpublished reports or opinions falsely or misleadingly represented or suggested to be . . . authoritative."[230] Moreover, literary references must reflect current scientific thinking. Thus, an advertisement will be false if it:

> Contains favorable information or opinions about a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information, or contains literature references or quotations that are significantly more favorable to the drug than has been demonstrated by substantial evidence or substantial clinical experience.[231]

Recall that Stuart's comparative safety claims in *E.R. Squibb & Sons v. Stuart Pharmaceuticals* failed for this very reason.[232]

This same principle applies to prohibit outdated references to a recognized authority, such as a medical textbook or treatise. Thus, FDA regulations prohibit the use of "a statement by a recognized authority that is apparently favorable about a drug but fails to refer to concurrent or more recent unfavorable data or statements from the same authority on the same subject or subjects."[233]

E. The Role of Substantive Regulatory Standards

Litigants in Lanham Act actions have attempted to use FDA regulatory standards and specific scientific determinations as

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> believe that a weight loss product should produce a difference of at least one-half pound per week between placebo and treatment groups. Such a weight loss would not only be statistically significant but clinically significant.
>
> . . . .
>
> If the results of a study cannot be applied to the actual conditions under which the tested product will be used they are meaningless. The [cited] study fails this test and its statistical significance does not, therefore, prove the value of the recommended dosage of Fibre Trim.

Id. at 54.

229 *Comments Regarding Health Messages*, *supra* note 22, at 13.

230 21 C.F.R. § 202.1(e)(7)(xiii) (1991).

231 21 C.F.R. § 202.1(e)(6)(iii) (1991).

232 *See supra* note 172.

233 21 C.F.R. § 202.1(e)(6)(viii) (1991).

both a sword and a shield. Over the years, these efforts have generally met with success.

In *Grove Fresh Distributors v. Flavor Fresh Foods*,[234] the court indicated that a party could rely on a competitor's violation of FDA regulations to establish a Lanham Act claim. The defendants advertised their product as "100% Orange Juice from Concentrate."[235] In fact, the juice contained additives and adulterants, including sugar. The plaintiff alleged that the defendants' advertising violated FDA regulations defining "orange juice from concentrate" and the general FD&CA provision prohibiting misbranding of food.[236]

In moving to dismiss, the defendants argued that the plaintiffs could not rely on violations of these provisions because the FD&CA does not provide for a private cause of action. The court rejected the defendants' argument and held that a plaintiff could rely on the violation of an FDA regulation to establish "the standard or duty" in a Lanham Act action.[237]

In Hobart Corp. v. Welbilt Corp.,[238] the plaintiff challenged the defendant's comparative advertising concerning their competing blenders. The court noted that when an advertisement involves safety claims, the FTC requires "competent scientific tests."[239] The court observed that the FTCA, which prohibits "unfair or deceptive acts or practices," is "analogous to the law under the Lanham Act."[240]

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234 720 F. Supp. 714 (N.D. Ill. 1989).

235 *Id.* at 715.

236 *Id.*

237 *Id.* The court reasoned:

> The fact that Grove Fresh refers to or relies on an FDA regulation defining orange juice to support its Lanham Act claim is not grounds for dismissal. Although courts have held that there is no private cause of action under the FD&CA, Grove Fresh has not brought suit directly under the FD&CA or its accompanying regulations. Grove Fresh relies on the FDA regulation merely to establish the standard or duty which defendants allegedly failed to meet. Nothing prohibits Grove Fresh from using the FD&CA or its accompanying regulations in that fashion.

Id. at 716.

238 No. 1:89 CV 1726, 1989 U.S. Dist. LEXIS 14447 (E.D. Ohio Oct. 4, 1989).

239 *Id.* at *12 (citing D. Thomson, 72 TRADEMARK REP. 385, at 388-84).

240 *Id.* at *12. The court found:

> Under that law, the Federal Trade Commission has said that it would consider the facts that a "reasonable prudent advertiser should have discovered before making the claim. When a medicinal efficacy claim is made, the standard of prior 'adequate and well-controlled scientific test[s]' will be applied. When the claim relates to safety, competent scientific test[s] will be required in advance. Substantially the same

Similarly, the court in *Upjohn Co. v. Riahom Corp.*[241] considered FDA standards in weighing the equities on a preliminary injunction application. There, the defendants characterized their product as a "cosmetic," and not a "drug," without conducting tests to determine its proper classification under the FD&CA.[242] In granting the preliminary injunction, the court found that, by proceeding without conducting the required tests, the defendants were "thumbing their nose" at FDA regulations.[243]

In a recent case, the court relied substantially on FDA scientific standards to evaluate the data underlying OTC drug establishment claims. In *McNeil-P.P.C. v. Bristol-Myers Squibb Co.*,[244] the manufacturer of AF Excedrin advertised that "AF Excedrin works better than ES Tylenol."[245] The court found that AF Excedrin contained caffeine whereas ES Tylenol did not. To support its superiority claim, the defendant relied on studies involving aspirin and caffeine. In challenging the claim, the plaintiff argued that studies involving aspirin and caffeine were not relevant to the efficacy of acetaminophen and caffeine. The court agreed, noting that the FDA's position coincided with the plaintiff's position.[246] The court also rejected other studies involving dosages outside of the OTC drug range. The court reasoned that FDA standards required dosages similar to those used by consumers.[247] In short, the court declined to credit the defendant's studies because they did not satisfy FDA standards.

Courts have also relied on a defendant's *compliance* with FDA standards to *reject* Lanham Act claims. In *American Home Products Corp. v. Johnson & Johnson*,[248] McNeilab claimed that AHP's aspirin labeling, prior to 1986, failed to warn that children and teenagers with viral diseases, who took aspirin products, incurred a significant risk of contracting Reyes Syndrome, a serious and often fatal condition. AHP defended by arguing that, prior to

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> standard has been applied to product performance claims that cannot readily be verified by the consumer." . . . . That standard provides a sensible approach. It requires that the advertiser make inquiry before making claims and that these tests be subject to replication and verification.

Id.

241 641 F. Supp. 1209 (D.Del. 1986).

242 *Id.* at 1225.

243 *Id.*

244 755 F. Supp. 1206 (S.D.N.Y. 1990).

245 *Id.* at 1208.

246 *Id.* at 1213.

247 *Id.*

248 672 F. Supp. 135 (S.D.N.Y. 1987).

1986, the FDA did not require a warning against this risk and had actually approved its labeling as adequate. The court thus addressed the question:

> whether a competitor has a cause of action under the Lanham Act based on the failure of an OTC drug manufacturer to include on the packages of its product a warning of a possible adverse side effect of the drug, where the existence of the side effect was the subject of scientific dispute and of intensive investigation by the FDA, which had found that no such warning was called for.[249]

The court held that AHP's compliance with FDA standards immunized it from liability on this claim under the Lanham Act. The court first noted: "[i]n unfair competition actions under state statutory or common law, it has been consistently ruled that compliance with FDA warning requirements is a complete defense."[250] The court observed that the rationale for this defense is "the need for uniformity in the regulation of advertising and labeling and a deference to the expertise of the responsible regulatory agency."[251] The court concluded: "the public interest is presumed to be adequately represented by the FDA, whose control over OTC drug labeling is . . . pervasive and complete."[252]

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249 *Id.* at 142.

250 *Id.* at 144. In product liability actions, by contrast, courts have declined to recognize compliance with FDA determinations as a complete defense. *See* Charles J. Walsh and Marc S. Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 FOOD DRUG COSM. L. J. 171, 185-94 (1986) (discussing cases in which state courts have imposed tort liability on manufacturers despite their compliance with FDA requirements).

The divergent standards conflict with public policy:

> If drug manufacturers follow state court requirements, they may violate FDA regulations and risk imposition of sanctions, including revocation of their permission to market the drug in question. On the other hand, manufacturers following the mandate of FDA and disregarding state common law requirements run the risk of substantial liability. To avoid that risk, manufacturers may decide to withhold drugs from the market indefinitely while awaiting more definitive test results. Either way, the public interest will suffer because people with serious and debilitating illnesses could be required to utilize less beneficial therapies.

Id. at 194.

251 *American Home Products*, 672 F. Supp. at 144.

252 *Id.* at 145. While recognizing AHP's *compliance* with the FDA's standards as a *defense*, the court also indicated that AHP's violation of those standards would support McNeil's Lanham Act claim. The court noted that pre-1986 packages of Anacin, without the Reyes Syndrome warning, remained on store shelves. The court wrote: "This is unthinkable. All pre-1986 packages should be recalled *immediately*. If AHP does not do so voluntarily . . . McNeil may move for reinstatement of the ninth counterclaim *nunc pro tunc*. AHP should obviously not be permitted to

The opportunity to further harmonize public and private regulation of scientific establishment claims in drug advertising, however, suffered a serious blow when the Third Circuit recently suggested that FDA standards may not play a substantial role in Lanham Act litigation. In *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*,[253] the controversy centered on whether a Lanham Act plaintiff "needs to show only that the defendant's advertising claims of its own drug's effectiveness are inadequately substantiated under FDA guidelines, or whether the plaintiff must also show that the claims are literally false or misleading to the public."[254]

In that case, Richardson-Vicks, Inc. (Vicks) claimed that its testing established the superiority of its cough medicine over a competing product marketed by Sandoz Pharmaceuticals Corporation (Sandoz). Yet, Vicks conceded that its testing would not suffice under FDA regulations for approval of a new drug. Indeed, the FDA had not approved Vicks's method of testing as appropriate to demonstrate the effectiveness of the product.

Sandoz pressed for the adoption of an "inadequate substantiation" standard under the Lanham Act based on the FDA's substantiation requirements. Sandoz correctly noted that the prohibition in the FTCA against "any false advertising"[255] is indistinguishable from the Lanham Act's prohibition against "any false description or representation."[256] Therefore, Sandoz argued, it would be absurd to find that a claim passed muster under the Lanham Act but not under the FTCA. Vicks countered that, under the Lanham Act, Sandoz still had to prove, through survey evidence, that Vicks's inadequately substantiated claims misled or deceived the consumer.[257]

The Third Circuit accepted Vicks's argument, citing a line of Lanham Act cases requiring explicit proof of consumer deception:

> We hold that it is not sufficient for a Lanham Act plaintiff to show only that the defendant's advertising claims of its own drug's effectiveness are inadequately substantiated under FDA guidelines; the plaintiff must also show that the claims are literally false or misleading to the public.[258]

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shield itself behind an FDA order with which it has not made every reasonable effort to comply in spirit as well as in letter." *Id.* at 146.

253 902 F.2d 222 (3d Cir. 1990).

254 *Id.* at 224.

255 15 U.S.C. § 52(a) (1988).

256 15 U.S.C. § 1125(a) (1988).

257 *Sandoz*, 902 F.2d at 227. While the case could be read to have involved an establishment claim, the decision did not characterize the claim as such.

258 *Id.* at 229. The court cited Procter & Gamble Co. v. Chesebrough-Pond's, Inc., 747 F.2d 114 (2d Cir. 1984), for the proposition that, while the FTC could

The Third Circuit also rejected Sandoz's contention that violation of FTC substantiation requirements should render an advertisement false or misleading per se under the Lanham Act:

> [T]he FTC's unique expertise and experience regarding consumer expectations allows it to determine for itself the level of substantiation consumers expect to support an advertising claim. If we were to hold that a Lanham Act plaintiff who has shown that a defendant's advertising claim was not supported by evidence sufficient to meet FDA testing regulations need not prove that consumers expect the claim to meet FDA testing requirements, then the Lanham Act plaintiff would stand in the same position as the FTC. Only the FTC is entitled to presume consumer expectations, however, because only the FTC has the necessary administrative experience and expertise.[259]

The Third Circuit's meaning in this passage is unclear. The court did not rely on any textual difference between the standards of liability under the FTCA and the Lanham Act. Rather, the court apparently reasoned that, while the FTCA and the FD&CA are designed to protect consumers, the Lanham Act is primarily designed to protect competitors.[260] In this analysis, the court ignored both the legislative history and the many authorities recognizing that the Lanham Act is designed to vindicate the public

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find a violation of the FTCA based merely on inadequate substantiation, "a Lanham Act plaintiff 'has the burden of proving not only that an advertisement is false, but also that the ad is misleading.' " *Sandoz*, 902 F.2d at 228.

259 *Id.* at 229.

260 The court wrote:

> The Lanham Act is primarily intended to protect commercial interests. . . . A competitor in a Lanham Act suit does not act as a 'vicarious avenger' of the public's right to be protected against false advertising. . . . Instead, the statute provides a private remedy to a commercial plaintiff who meets the burden of proving that its commercial interests have been harmed by a competitor's false advertising.

Id. at 230.

The Court made a similar point concerning the FD&C Act: "The FD&C Act . . . is not focused on the truth or falsity of advertising claims. It requires the FDA to protect the public interest by 'pass[ing] on the safety and efficacy of all new drugs and . . . promulgat[ing] regulations concerning the conditions under which various categories of OTC drugs . . . are safe, effective and not misbranded.' " *Id.* at 230 (quoting American Home Prod. v. Johnson & Johnson, 436 F. Supp. 785, 797-98 (S.D.N.Y. 1977), *aff'd*, 577 F.2d 160 (2d Cir. 1978)). The Third Circuit's reasoning on this score is weak. As we have seen, the FDA has adopted a complete body of advertising regulations pursuant to its authority under the FD&C Act. These regulations are, by their terms, directly focused "on the truth or falsity of advertising claims."

interest.[261]

Likewise, the Third Circuit's argument for deference to regulatory judgments cuts the other way. When the FDA or FTC has promulgated a specific advertising rule based on its expertise, the agency has already found that a violation of the rule would mislead consumers. If courts should defer to administrative expertise, they should also recognize and apply the rule in Lanham Act litigation.

In terms of pharmaceutical advertising, both the FDA and the FTC are charged with policing truth in the marketplace. Their mission — to interdict "unfair and deceptive acts or practices" — is indistinguishable from the ultimate regulatory mission of private litigation under section 43(a) of the Lanham Act. Moreover, several public policy interests are served by coordinating public regulation of false advertising with private (Lanham Act) regulation of the same domain.

First, coordination would permit public regulation under the FTCA or FD&CA and private regulation under the Lanham Act to send a single, clear and uniform message to advertisers. This would, in turn, minimize undesirable overbreadth and its undesired chilling effect with respect to truthful advertising.[262]

Second, coordinating the two bodies of regulatory authority would conserve administrative and judical resources by allowing them to work in tandem. If the FTC or the FDA takes an aggressive position, and promptly corrects an abuse in the marketplace, a competitor may be less likely to resort to private litigation. Conversely, when these administrative agencies fail to take action, perhaps to

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261 The Third Circuit's analysis, moreover, is particularly unpersuasive in relation to drug advertising. Drugs are the most heavily regulated products on the market today. FDA regulations govern, in exquisite detail, drug development, marketing, labeling, and advertising. Physicians and consumers alike may not know the precise terms of the FDA regulations, but they are surely aware of the FDA's involvement in these areas. Because physicians and consumers would unquestionably expect drug advertising to comply with FDA regulations, survey data should not be required to confirm that obvious proposition. A requirement of survey data for that purpose would vastly complicate and delay a Lanham Act litigation, thus undermining the Act's dual policy objectives: the protection of both aggrieved competitors and the public welfare. In the context of drug advertising, therefore, courts should incorporate specific advertising regulations adopted by federal agencies, like the FDA, if they are designated to prohibit false and misleading claims. Thus, based on the FDA's substantiation requirement, all scientific representations should be treated as though they were explicit establishment claims for purposes of Lanham Act law.

262 *See* Jeffrey P. Singdahlsen, *The Risk of Chill: A Cost of the Standards Governing the Regulation of False Advertising Under Section 43(a) of the Lanham Act*, 77 VA. L. REV. 1339 (1991)(vague standards unduly chill the dissemination of useful comparative advertising).

conserve their resources, competitors may be willing to bear the litigation costs. In either situation, the result should be the same.

Third, coordination would advance the consumer's welfare — as contemplated by both bodies of regulatory law — by clarifying and standardizing the meaning of scientific establishment claims in advertising. Physicians and consumers would be assured that all scientific establishment claims meet a single standard, whatever that standard might be, rather than a patchwork of differing standards. The differing standards might confuse the important signal of comparative advertising and, hence, detract from its social utility.

Fourth, administrative agencies are better equipped to apply important scientific principles relevant to evaluating scientific establishment claims in advertising. The agencies have rule making, technical and scientific expertise, as well as institutional advertising expertise. Courts, on the other hand, proceed on an ad hoc basis with the assistance only of private litigants. Thus, we may expect faster and better results in Lanham Act cases if the courts embrace the handiwork of the administrative agencies.

V. Conclusion

When a drug manufacturer claims through advertising that scientific data establish the superiority of its product over another drug on the market, whether in terms of safety or efficacy, the message is a powerful and important one. Medications, and correct information about them, are vital to our well-being.

Scientific establishment claims in comparative drug advertising are subject to complementary systems of regulation. The FDA and FTC directly regulate these claims on the public's behalf to ensure that they are not false or misleading. Under the Lanham Act, aggrieved pharmaceutical manufacturers may also act to interdict false or misleading scientific establishment claims. Congress created this dual scheme of regulation, governed by nearly identical standards, to protect the public interest in truthful advertising.

Over the years, the FDA and FTC have carefully considered the important public policies involved in the regulation of drug advertising. These agencies have addressed the nature of the scientific evidence essential to sustain scientific establishment claims in drug advertising and have also articulated regulatory standards to govern those claims.

In Lanham Act litigation involving scientific establishment claims, courts should defer to the scientific and policy judgments

of these agencies. Through coordinated standards, both bodies of law would gain strength. Moreover, coordinated standards would enable courts to resolve Lanham Act litigation with greater efficiency and effectiveness and thus foreclose serious threats to the public welfare.