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# Description and Analysis of FTC Order Provisions Resulting From References in Advertising to Tests or Surveys

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## Description and Analysis of FTC Order Provisions Resulting From References in Advertising to Tests or Surveys

Ivan L. Preston\*

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#### I. INTRODUCTION

#### A. Scope of the Article

This is a study of Federal Trade Commission<sup>1</sup> (FTC) prosecutions of advertisements that misrepresent the existence of tests or surveys as support for selling claims.

If the essential challenge of American advertising is to create belief within a marketplace of intense competition, then the essence of the advertiser's task is to make his product claim credible in the minds of consumers who are under constant invitation to favor a competitor. Thus, it is important not merely to describe the product's worthiness, but to establish an underlying support for the claim so as to compel the consumer's belief in its truth. The most common means the advertiser employs in establishing credibility is to effect a proof by means of the aura which surrounds the scientific test or survey.

Such evidence, when available, is likely to be used in advertising. In some cases, such evidence is used even when not available because it has been contrived and presented to the public as if true. In the 1960's, a shaving cream was presented on television in a contrived test that misrepresented its ability to enable a razor blade to shave sandpaper. The practice was proscribed, but in 1985 the maker of an analgesic cream was told to cease claiming superiority absent proof of the implied representation that the claim was supported by scientific tests. The intervening years have seen dozens of similar orders against test or survey misrepresentations.

Although orders proscribing such misrepresentations have been mentioned in various articles,<sup>2</sup> no source has provided a complete catalog or categorization of the many order provisions in these cases. The considerable impact of the FTC on the area is not readily discernible without such an overview. In particular, there is a tendency for misrepresentations to become more subtle over time. Apparently,

<sup>1.</sup> For F.T.C. authority and actions generally, see Kintner and Smith, The Emergence of the Federal Trade Commission as a Formidable Consumer Protection Agency, 26 MERCER L. REV. 651 (1975); Pitofsky, Beyond Nader: Consumer Protection and the Regulation of Advertising, 90 HARV. L. REV. 661 (1977); Hammer, F.T.C. Knights and Consumer Daze: The Regulation of Deceptive or Unfair Advertising, 32 ARK. L. REV. 446 (1978); Comment, The Ad Substantiation Program: You Can Fool All of the People Some of the Time and Some of the People All of the Time, But Can You Fool the F.T.C.?, 30 AM. U. L. REV. 429 (1981) [hereinafter Ad Substantiation]; Holmes, F.T.C. Regulation of Unfair or Deceptive Advertising: Current Status of the Law, 30 DE PAUL L. REV. 555 (1981); Vercammen and Smith, Advertising and the F.T.C.: Less Regulation Can Mean More Consumer Protection, 8 CORP. L. REV. 49 (1985) [hereinafter Less Regulation].

<sup>2.</sup> Ad Substantiation, supra note 1; Barnes, The Significance of Quantitative Evidence in Federal Trade Commission Deceptive Advertising Cases, 46 LAW & CONTEMP. PROBS. Autumn 1983, at 25; Handler, Pfizer Revisited: From "Reasonable Basis" to "Establishment Claims" in Advertising Substantiation, 38 FOOD DRUG COSM. L.J. 325 (1983); Less Regulation, supra note 1.

when a strongly explicit form of misrepresentation has been forbidden, advertisers fall back to less obvious forms.

Thus, while advertisers such as the shaving cream maker have reduced their tendency to misrepresent with explicit demonstrations or tests, they have shifted to referring to tests and surveys as proof without showing them in the ads. Or, they have used the representation that tests or surveys exist not as proof but merely as support for the product claims. Since the early 1970's, however, advertising regulation has fallen back correspondingly to prohibit such references to tests or surveys when they do not support the claims they purport to substantiate.

Of even greater subtlety and frequency has been the advertising that makes no explicit reference to tests or surveys, but which by its nature implies that a test, survey or equivalent scientific evidence exists as support for the claims. This is the ultimate fallback position, because the advertiser makes no explicit references that may be challenged. Again, advertising regulation has fallen back in tandem, prohibiting such implications. Thus, the broad overview offered here shows that the early cases primarily involve explicit claims about tests and surveys, while the later cases concentrate on references alleged to be implied merely by existence of the product claims.

Another emerging pattern is that of an increase in standards to prohibit a wide variety of common yet inadequate test and survey practices. Whereas advertisers' past expectations appear to have identified the methodological criterion as being merely a showing that a test or survey was conducted, the recent FTC record has specified numerous requirements for performance at valid scientific levels. The accumulated thrust of these requirements, which have raised scientific standards tremendously, has not heretofore been summarized.

### B. Method of Analysis

By the nature of the topic, this article constitutes an interdisciplinary study, examining physical science and social science methods and knowledge as drawn from the testimony of numerous expert witnesses in those fields. Fittingly, the method of analysis is one familiar to the social scientist, a content analysis.

The units of study consist of those FTC order provisions that pertain to tests and surveys. The method involves separating all such provisions into groups in accordance with their similarities and differences. The evolving categories then are named and defined, and their significance is discussed.

In most cases, the FTC order provisions are consistent with the nature of the misrepresentation—that is, the provision forbids the precise type of violation that has been charged or found to occur. There are exceptions, however, in which an order provision falls into a category different from that specified in the violation. Such cases are categorized according to the provision, because that is the unit of study.

For each order, only those provisions that involve surveys or tests are cited. This means many of the orders mentioned are described only partially in the article. Further, two or more parts of the same order often are described in separate sections because of assignment to different categories.

Case contents that describe or explain the order provisions are discussed. In many consent orders, the complaint allegations are the only source of explanation. In the litigated cases, the initial decision of the administrative law judge (ALJ, called Hearing Examiner in the earlier cases) and the opinions of the Commission are available. For some litigated cases, there are appellate opinions.

The materials examined were identified by searches on LEXIS for FTC cases containing the terms "test," "survey," "reasonable basis," and "substantiation." The LEXIS file begins in 1950. The assumption that few earlier cases exist is suggested by finding only one from the 1950's and few from the early 1960's. Casual search has identified a few cases prior to 1950, but that era produced no systematic treatment of tests and surveys.

Another analytical decision is that tests and surveys are discussed simultaneously to the extent possible, but in parallel subsections to the extent necessary. Tests and surveys generally are defined separately, despite one Commission opinion that "'test' shall include demonstrations, experiments, surveys, reports and studies."<sup>3</sup> The more typical position is that "[t]ests, which ascertain scientifically product specifications and quality, are different from surveys, which measure popular opinion."<sup>4</sup> Actually, some surveys in FTC cases measured phenomena other than opinion—prices, for example, at which a product sells, or the number of jobs at given salaries secured by graduates of trade schools. Because of that, surveys are defined herein as involving observations of nonuniform populations, i.e.,

<sup>3.</sup> Ford Motor Co., 93 F.T.C. 873, 881 (1979). The statement was probably written for the limited purpose of creating a generic term for the phenomena involved in the particular case.

<sup>4.</sup> Litton Indus., Inc. v. F.T.C., 676 F.2d 364, 372 (9th Cir. 1982) (modified to involve only surveys and not tests).

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those anticipated to have significant uncontrolled variation from unit to unit.

Tests, by contrast, are made on objects whose characteristics are controlled; they are anticipated to be uniform (although uniformity is not always perfectly achieved). People in stores all over the nation, for example, upon purchasing a cake of Dial Soap expect to get essentially the same item. Accordingly, tests and surveys are distinguished here, but also are treated in parallel format because of the similar treatment they receive from the FTC.

#### C. Structure of the Article

The structure reflects the categories derived from the content analysis, based on the types of FTC order provisions. The categories vary mainly by the strength with which the advertising references are made. Two ways of varying such strength are by mentioning the test or survey explicitly or implicitly, the latter being the weaker. These variations are further subdivided as follows.

The strongest type of reference occurs in ads that show tests actually taking place (surveys are not amenable to this treatment). The consumer does not merely hear about the findings, but personally sees them created. These presentations are held to be misrepresented as constituting demonstrations of the proof of the accompanying product claim. This is called, herein, the "Demonstrated Proof Misrepresentation."

The second strongest type of reference occurs in ads that cite the existence of a test or survey. The ad either mentions it, or shows or quotes from a document that reports it, or depicts the laboratory or other setting in which it took place. As with the first category, the advertising is held to misrepresent the cited test or survey as proving the truth of the accompanying claim. This is called the "Cited Proof Misrepresentation."

A third category also involves ads that cite tests or surveys, absent explicit references that they constitute proof of the accompanying claim. Because it is held to misrepresent the cited test or survey as supporting evidence, it is called herein the "Cited Evidence Misrepresentation." The three categories discussed thus far involve explicit mentions of tests or surveys, albeit sometimes indirectly by related terminology or nonverbal means.

Ads in the fourth category involve no such explicit references. Rather, they are alleged to imply falsely that prior to the advertising a reasonable basis existed for believing the claims, or, in alternative wording, substantiation for the truth of the claims existed.<sup>5</sup> The reasonable basis or substantiation could only be a test or survey, or testlike or survey-like evidence, and such material either was nonexistent prior to the advertising or was not of a quality to constitute the requisite support. This category is called herein the "Reasonable Basis/Substantiation Misrepresentation" or the "RB/S Misrepresentation."

The four categories just discussed represent the major types of misrepresentations involving tests and surveys. Section II discusses the "Demonstrated Proof Misrepresentation," Section III the "Cited Proof Misrepresentation," and Section IV the "Cited Evidence Misrepresentation." Section V discusses the conceptualizing of the "RB/ S Misrepresentation," and the following sections discuss three kinds of order provisions resulting from it. Some provisions specify a test and/or survey as a firm requirement (Section VI). Other provisions specify a test and/or survey, but allow alternatives of test-like or survey-like evidence (Section VII). Others specify test-like or surveylike evidence without mentioning tests or surveys explicitly (Section VIII). Sections II-VIII thus depict the aforementioned progression from use of explicit claims to use of more subtle implied claims. The explicit claims discussed in the earlier sections generally predate the implied claims discussed later.

A further topic is the specifications offered by the FTC as to acceptable and nonacceptable characteristics of tests and surveys. This is the portion of the article that most specifically demonstrates the Commission's imposition of test and survey standards of significantly higher quality than found in the exhibits offered by many respondent advertisers.<sup>6</sup> Section IX discusses these specifications.

Finally, Section X examines additional order provisions reflecting other types of test and survey misrepresentations. They include overclaiming of results, the parallel topic of underclaiming, misrepresen-

<sup>5.</sup> Considerable discussion in these cases is devoted to the process of implication, whereby an advertisement conveys meanings to consumers over and above its literal content. F.T.C. treatment of such implications is in itself a topic worth far more study than can be accommodated here. This article, therefore, does not question the legal rationale nor factual evidence for concluding that consumers see ads to be conveying the various implications cited. For a thorough discussion, see Preston, *The FTC's Handling of Puffery and Other Selling Claims Made "By Implication"*, 5 J. BUS. RES. 155 (1977); Rotfeld and Preston, *The Potential Impact of Research on Advertising Law*, 21 J. ADV. RES. 9 (1981).

<sup>6.</sup> Tests and surveys also occur prominently in litigated F.T.C. cases as evidence for determining the meanings implied to consumers by an advertisement's literal content. That topic is not undertaken here. Also not included are cases involving the misrepresentation by door-to-door or telephone salespersons that they are conducting surveys when they are actually making sales pitches. Such cases do not involve referencing of such surveys as the basis for accompanying product claims.

tations about experts, provisions about consumer endorsements or testimonials related to tests and surveys, general misrepresentation provisions, records maintenance provisions, advertising agency defense provisions, test requirements apart from substantiation, contradictory or inconsistent claims, misuse of name or authorization of government or testing organizations, failure to forward evidence, and requirements to disclose test limitations. Section XI presents a brief statement of conclusions.

#### II. THE DEMONSTRATED PROOF MISREPRESENTATION

The strongest type of reference to tests in FTC advertising cases occurs in ads that depict product performance tested before the consumer's eyes, with an accompanying explicit or implicit representation that what is seen proves the product claims. Surveys, along with some types of tests, are not amenable to such treatment because they do not produce outcomes that can be demonstrated before an advertising audience.

The "Demonstrated Proof Misrepresentation" began when Rapid Shave was "shown" applied to sandpaper which was then "shaved."<sup>7</sup> In reality, the camera had photographed loose grains of sand sprinkled on a sheet of plexiglas. It was impossible to conduct such a demonstration with real sandpaper. The order provision, therefore, prohibited the advertiser from doing the following:

[u]nfairly or deceptively advertising . . . by presenting a test, experiment or demonstration that (1) is represented to the public as actual proof of a claim made for the product which is material to inducing its sale, and (2) is not in fact a genuine test, experiment or demonstration being conducted as represented and does not in fact constitute actual proof of the claim, because of the undisclosed use and substitution of a mock-up or prop instead of the product, article, or substance represented to be used therein.<sup>8</sup>

The Commission found that to claim the consumer was seeing proof was deceptive even if the claim was true. Colgate argued that

<sup>7.</sup> Colgate-Palmolive Co., 59 F.T.C. 1452 (1961), rev'd and remanded, Colgate-Palmolive Co. v. F.T.C., 310 F.2d 89 (1st Cir. 1962); revised, 62 F.T.C. 1269 (1963); remanded, 326 F.2d 517 (1st Cir. 1963), rev'd and enforced, 380 U.S. 374 (1965). (Colgate's advertising agency, Ted Bates, also a named party).

<sup>8.</sup> Colgate-Palmolive, 62 F.T.C. at 1282. The complaint referred to the depiction as a demonstration rather than test, which may be fitting inasmuch as "test" may suggest the formality of work done by a scientist in a laboratory. The announcer's voice, however, referred to "this sandpaper test," and the Commission opinions referred to the same with no discussion of terminology. The Commission probably used "test" to emphasize that the advertiser was claiming to show proof. The provision's reference to a "test, experiment or demonstration" became a formula used in many future cases.

if the benefits were as represented, the consumer could not be hurt, but the Commission held that this:

would flout the principle implicit in the multitude of cases [involving misrepresentation of a variety of other sorts] already decided . . . . The vice assailed in these cases is the use of a falsification of fact, extrinsic to the objective value of the product, to sell that product, whether or not it may deserve to be bought on its own merits.<sup>9</sup>

Three cases shortly thereafter involved the same elements, but their provisions mentioned demonstrations rather than tests.<sup>10</sup>

9. Colgate-Palmolive, 59 F.T.C. at 1466. "[T]he 'proof' was not proof at all . . . [and yet] the 'proof' offered was a material element of the advertising; without it, the advertiser might not have succeeded in selling the product." *Id.* "[The] respondents must have thought so, or else they would not have emphasized the pictorial 'sandpaper test' in the expensive television advertisements of their product." *Id.* at 1467. Later the F.T.C. added that:

The product may in fact be all the purchaser thinks it to be; but if he has been induced to buy it by the seller's fraud, injury is done both to the advertiser's competitors and to the public.... Regardless whether consumers are 'injured'... honest competitors are injured—because some or many of such sales have been made at their expense.

*Colgate-Palmolive*, 62 F.T.C. at 1273-74. The Supreme Court, reversing the First Circuit's remand, noted that Colgate had argued, based on the accepted premise that only material misrepresentations may be held in violation, that:

the only material facts are those which deal with the substantive qualities of a product. The Commission, on the other hand, submits that the misrepresentation of *any* fact so long as it materially induces a purchaser's decision to buy is a deception prohibited... The Commission's interpretation of what is a deceptive practice seems more in line with the decided cases than that of respondents.

Colgate-Palmolive, 380 U.S. at 386-87.

10. When the television viewer was "shown" how a competing brand compared unfavorably to Rise shaving cream, the substance actually presented on screen was no competitor but a special formula that "contained properties which caused it to disappear rapidly and appear to dry out immediately after being applied to the face of the actor." Carter Prods. Inc., 60 F.T.C. 782, 786 (1962), modified, Carter v. F.T.C., 323 F.2d 523 (5th Cir. 1963), modified order, 63 F.T.C. 1651 (1963).

In its own defense, respondent . . . offered . . . certain tests . . . to support its claim that more than 50 percent of the competing aerated shaving creams on the commercial market dry out faster than "Rise." Even assuming this contention to be true, this does [not] make the representation . . . any less a misrepresentation.

Carter Prods., 60 F.T.C. at 787. The context compels belief that the word shown in brackets was meant to be included. "[O]ur views with respect to the use of television demonstrations that convey false or deceptive impressions to the public were fully set forth in our opinion in the matter of *Colgate*... and the rationale of that decision is equally applicable here." *Id.* at 795. Carter was ordered to cease:

(a) Disparaging . . . through the use of false or misleading pictures, depictions or demonstrations. . . . (b) Representing . . . that pictures, depictions or demonstrations . . . accurately portray or depict the superiority of any product over competing products when such portrayal or depiction is not an accurate comparison of such product with competing products.

*Carter Prods.*, 63 F.T.C. at 1652. The appellate court substituted "an accurate" for "a genuine and accurate" because "accurate" allows some variation from absolute truths and "genuine" does not. *Carter*, 323 F.2d at 532. The court did not want to require that "the actual products used in the comparison must be the real thing," but only that the comparison not be deceptive. *Id.* 

Libbey-Owens Ford involved similar advertising and order provisions, the opinion

The cases thus far involved the consumer "seeing" something he was not really seeing. Another Colgate case<sup>11</sup> introduced the type of test or demonstration that was true as seen, yet still failed to prove the claim it accompanied. Baggies sandwich bags were truthfully shown keeping a sandwich dry under water, a test the competitor failed. Falsely claimed, however, was that the test proved Baggies superior for keeping food fresh under ordinary conditions. The result was an order to cease "[a]dvertising any such product by presenting a test, experiment or demonstration or part thereof that is presented as actual proof of any fact or product feature that is material to inducing the sale of the product, but which does not actually prove such fact or product feature."<sup>12</sup>

Sun Oil's<sup>13</sup> claims about engine power had been accompanied by illustrations of an automobile pulling railroad cars, or pulling a trailer to the top row of a stadium. Although the complaint charged the illustrations to be represented as proving the claims, the decision did not discuss the point, probably because it found the claims were not true. Complaint counsel asked for an order provision<sup>14</sup> as follows, but the provision actually written omitted the portion shown in brackets:

cease and desist from  $\ldots$  [a]dvertising any such product by presenting evidence including tests, experiments or demonstrations, or the results thereof, or any other evidence [that appears or purports to be proof] of any fact or product feature that is material in inducing the sale of the product which is

stating that the "same considerations discussed in *Colgate* apply with equal force in this proceeding." Libbey-Owens Ford Glass Co. & General Motors Corp., 63 F.T.C. 746, 783 (1963), *affirmed*, Libbey-Owens-Ford Glass Co. v. F.T.C., 352 F.2d 415 (6th Cir. 1965). The appellate court agreed to the reliance on *Colgate*. *Libbey-Owens Ford*, 352 F.2d at 417-18. The provisions referred to "any picture, demonstration, experiment, or comparison." *Libbey-Owens Ford*, 63 F.T.C. at 786. *See also* Ideal Toy Corp., 64 F.T.C. 297 (1964).

11. Colgate-Palmolive Co., 77 F.T.C. 150 (1970) (consent) (Colgate's advertising agency, Masius, also a named party).

12. Id. at 153. Bishop Industries received the same provision. Bishop Indus., 77 F.T.C. 380, 383 (1970) (consent). A similar provision for *Campbell Soup* referred to "tests, experiments or demonstrations, or the results thereof, or any other evidence that appears, or purports, to be proof . . . ." Campbell Soup Co., 77 F.T.C. 664, 676 (1970) (consent). Four others in the next two years were similar. Rhodes Pharmacal Co., Inc., 78 F.T.C. 680, 685 (1971); Borden, Inc., 78 F.T.C. 686, 689 (1971); Union Carbide Corp., 79 F.T.C. 124, 127 (1971); American Home Prods. Corp., 81 F.T.C. 579, 585, 586 (1972) (all consent) (American's agency, Cunningham and Walsh also a named party). The provisions in *Borden* and *Union Carbide* emphasized distortions and exaggerations.

13. Sun Oil Co., 84 F.T.C. 247 (1974) (litigated) (agency William Esty also a named party).

14. Id. at 275.

not evidence which actually proves such fact or product feature.<sup>15</sup>

Less than a year later the omitted phrase was used in provisions otherwise similar to that of *Sun Oil*. Ford showed a car lifted by a crane that held it only by the steel guard rails embedded within its doors.<sup>16</sup> This was misrepresented as proof that the lateral strength of the embedded rails, which is what protects against force exerted horizontally, was that of highway guard rails.

In a Standard Oil of California advertisement, a claim to eliminate pollutants was supported by demonstrating a plastic bag attached to a car exhaust, accompanied by "Here's proof."<sup>17</sup> Before using the gasoline the bag was filled with smoke; afterward it was clear. However, the "before" effect was created by prior artificial production of heavy engine deposits, not typical of cars on the road. In addition, much pollution is invisible and could remain even though the visible smoke was eliminated.

Another Socal ad showed a meter labeled "Exhaust Emissions" indicating a reduction of 80 of the dial's 100 units, an apparent 80 percent change.<sup>18</sup> But the meter measured only one pollutant, and the reduction was much less than 80 percent for that one. Accordingly, an additional provision forbade representing that "[a]ny machines, measuring devices or technical instruments have particular characteristics or capacities when such is not the fact . . . ."<sup>19</sup>

Sears, Roebuck's ads showed demonstrations purporting to prove the false claim that its dishwashers would clean all dishes, pots, and pans without prior rinsing or scraping. Its agency consented to an order specifically prohibiting a "Demonstrated Proof Misrepresentation."<sup>20</sup> Sears, following litigation, received an order provision discussed in Section VII which generally forbade representations

18. Standard Oil Co. of Cal., 84 F.T.C. 1401, 1473 (1974).

19. Id. at 1490.

<sup>15.</sup> Id. at 280. "Complaint counsel cites the decision of the Commission in Colgate [Rapid Shave] as support for this provision." Id. at 275. However, "[T]he provision in the order pertaining to Colgate was not identical with the provision now proposed. Accordingly, the provision will be modified to conform with that prescribed in the Colgate case." Id. No commentary explained why the excised phrase brought the provision closer to Colgate. The decision gave no explanation as to how "tests, experiments, or demonstrations" might differ, or why tests were cited although not involved.

<sup>16.</sup> Ford Motor Co., 84 F.T.C. 729, 735 (1974); J. Walter Thompson Co., 84 F.T.C. 736, 742 (1974) (agency for Ford) (both consent), *affirmed*, Ford Motor Co. and J. Walter Thompson Co. v. F.T.C., 547 F.2d 954 (6th Cir. 1976).

<sup>17.</sup> Standard Oil Co. of Cal., 84 F.T.C. 1401, 1470 (1974), modified (no changes involving tests), Standard Oil Co. v. F.T.C., 577 F.2d 653 (9th Cir. 1978), modified, 95 F.T.C. 866 (1980) (repeated word-for-word at 96 F.T.C. 380 (1980) without explanation). Standard's agency BBD & O also a named party). See also STP Corp., 87 F.T.C. 56, 59, 61 (1976), in which a screwdriver was dipped into the oil additive, whereupon a strong man was shown unable to hold it by the tip end. That demonstrated slipperness, but did not prove the additive would help oil lubricate better. (STP's agent, Stern, Walters & Simmons also a party).

<sup>20.</sup> J. Walter Thompson Co., 94 F.T.C. 331, 338 (1979).

about product performance absent substantiation.<sup>21</sup> This included misrepresentations of demonstrations of such performance, but no explanation was offered for the different wording. Whether such general coverage presages the dropping of specific recognition of the "Demonstrated Proof Misrepresentation" in the future is hard to say, but there have been almost no charges of such misrepresentation since *Sears*.<sup>22</sup> The charges and consequent provisions that *have* occurred are sufficient to prohibit the "Demonstrated Proof Misrepresentation," but they omit specific guidance concerning it.

The "Demonstrated Proof Misrepresentation" was the most blatant, the earliest to gain prominence, and the earliest to wane, of the types seen in this article. The trend over time has been to more subtle misrepresentations.

#### III. THE CITED PROOF MISREPRESENTATION

In this category the test or survey is explicitly cited but not shown in action. The ad misrepresents explicitly or implicitly that the cited test or survey proves the product claim. Tests and surveys are discussed separately, with development and early history discussed under tests.

#### A. Tests

#### 1. Development and Principal Cases

Although this category generally came later than the "Demonstrated Proof Representation," there was an early order telling the advertiser to "cease and desist from: . . . (1) Disseminating . . . any advertisement . . . which advertisement represents . . . [t]hat the therapeutic value of said preparation has been proven clinically by tests made in a hospital."<sup>23</sup> The FTC apparently felt such tests could never be made, and therefore issued an outright prohibition of the proof claim.

However, two later advertisers charged with the same explicit fal-

<sup>21.</sup> Sears, Roebuck, & Co., 95 F.T.C. 406, 525 (1980), affirmed, Sears, Roebuck & Co. v. F.T.C., 676 F.2d 385 (9th Cir. 1982).

<sup>22.</sup> North Am. Philips, No. 842-3177, F.T.C. slip op., at 4 (Feb. 10, 1986)); National Energy Assocs., No. C-3179, F.T.C. slip op., at 9 (Feb. 5, 1986) (both consent).

<sup>23.</sup> Foley & Co., 48 F.T.C. 670, 680 (1952). The same occurred with International Safe-T-Trac, 79 F.T.C. 318, 325 (1971), LeConte Cosmetics, Inc., 87 F.T.C. 1348, 1355 (1976); North Am. Phillips Corp., 101 F.T.C. 359, 364 (1983); McCaffrey & McCall, Inc., 101 F.T.C. 367, 368 (1983) (all consent).

sity were given orders that conceded the absent proof might someday be produced. They were told to cease:

representing that said product or products have been tested, and have passed such tests . . . or that tests have demonstrated that its products are superior to other products tested . . . unless and in fact, tests have actually been performed and the results establish that such representations are true.<sup>24</sup> Disseminating . . . any advertisement . . . which in any manner makes reference to scientific or medical tests or studies as allegedly substantiating any representation or claim as to the effectiveness or performance of any such product unless scientific or medical tests or studies in fact substantiate such representation or claim.<sup>25</sup>

These provisions illustrate the now-familiar "unless" form of order provision, in which the test or survey reference is permitted if true. Typically, it had not been true, either because it did not exist or because it did not prove the product claim. But the "unless" provision recognized that a test or survey adequate to constitute proof might in the future exist, and that the claim thereupon could be permitted.

Such a conditional provision is inappropriate for the "Demonstrated Proof Misrepresentation," because the latter represents a test conducted in a specific way. Because such a test cannot support what it claimed, the appropriate remedy is the outright prohibition. However, in the "Cited Proof Misreprentation" the test or survey is not described but only represented to exist. That leaves open the possibility of concluding that an appropriate test or survey *could* exist.

Standard Oil of California was charged with a "Cited Proof Misrepresentation" in addition to the "Demonstrated Proof Representation." It was told to cease representing that:

Warner-Lambert was charged with representing "that the latest or most recent tests conducted by or for it, or available to it, prove that children who gargle with Listerine twice a day have fewer and

How did the "Cited Proof Misrepresentation" occur along with the "Demonstrated Proof Misrepresentation?" It was because the demonstrations not only amounted to misrepresentations per se but also implied the existence of more formal scientific tests:

'[H]ere's proof' and 'You're about to see proof'... clearly invite the assumption that what follows is based on tests or other reliable substantiation. The appearance in the demonstrations of complicated measuring instruments and white-coated 'technicians' contributes to the impression that scientific testing is behind the advertisements.

Id. at 1472.

Tests, demonstrations, research or experiments have been conducted which prove or substantiate any of said representations . . . Unless and only to the extent that each and every such representation is true and has been fully and completely substantiated by competent scientific tests.<sup>26</sup>

<sup>24.</sup> Matsushita Electric of Hawaii, Inc., 78 F.T.C. 353, 357 (1971) (consent).

<sup>25.</sup> J. B. Williams Co., Inc., 79 F.T.C. 410, 419 (1971) (consent). See also Wasem's, Inc., 84 F.T.C. 209, 213 (1974) (consent).

<sup>26.</sup> Standard Oil Co. of Cal., 84 F.T.C. 1401, 1490 (1974). The order for its agency, BBD&O, was similar, with the "unless" portion stating, "Unless and only to the extent that respondent has a reasonable basis for such representation based upon competent scientific tests by it or its client." *Id.* at 1491.

milder . . . colds than do those children who do not so use Listerine."<sup>27</sup> The company had based this claim on a series of tests lasting twelve years, but had received disconfirming evidence in a recent second series of tests.

The ALJ noted that "[a] representation that tests prove a claim is a representation as to the most recent tests available," yet he also found extenuating circumstances.<sup>28</sup> The respondent had stopped the claim after the second year of the disconfirming studies, although not after the first year. The twelve-year series had been reliable enough that "respondent cannot be said to have acted unreasonably when it waited until it received an indication of what the second year of the [second series] would show before it abandoned reference to the [first series] in its advertising."<sup>29</sup> Accordingly, the charge of a "Cited Proof Misrepresentation" was abandoned.

In Crown Central, the ALJ was unwilling to find references made to tests as proof, because only a single test was advertised, and only in a footnote "in small type not prominent."<sup>30</sup> The Commission reversed this with the comment that "[a] specific study is cited . . . ."<sup>31</sup> The resulting order provision<sup>32</sup> was exactly as for Standard Oil of California.

In all of the cases mentioned thus far, companies misrepresented that proof existed for a claim. In *National Commission on Egg Nutrition*,<sup>33</sup> the principal misrepresentation was that *no* scientific proof existed that eating eggs increases the risk of heart attack or heart disease.<sup>34</sup>

Respondents do not deny that well-qualified experts have relied upon competent and reliable scientific studies in hypothesizing a relationship between dietary cholesterol and heart disease. Respondents argue, however, that . . . such studies lend little or no support to the diet-heart disease hypothesis, and that the studies consequently do not rise to the level of "evidence that eating eggs

29. Id.

30. Crown Cent. Petroleum Corp., 84 F.T.C. 1493, 1547 (referring to 1529 n. 40) (1974), modified, Crown v. F.T.C., 530 F.2d 1093 (D.C. Cir., 1976) (no published opinion), modified order, 88 F.T.C. 210 (1976).

31. Crown Cent., 84 F.T.C. at 1549.

32. Crown Cent., 88 F.T.C. at 210.

33. 88 F.T.C. 89 (1976), modified, NCEN v. F.T.C., 570 F.2d 157 (7th Cir. 1977), modified order, 92 F.T.C. 848 (1978).

34. Egg Nutrition, 88 F.T.C. at 180. The ads tended not to refer to proof, the ALJ said, but "any distinction between 'proof' and 'evidence' would not be generally recognized by the public in the context of respondents' advertisements." *Id.* at 112.

<sup>27.</sup> Warner-Lambert Co., 86 F.T.C. 1398, 1401 (1975), modified, Warner-Lambert v. F.T.C., 562 F.2d 749 (D.C. Cir. 1977) (no change involving tests), cert. denied, 435 U.S. 950 (1978), modified order, 92 F.T.C. 191 (1978).

<sup>28.</sup> Warner-Lambert, 86 F.T.C. at 1465.

will increase the risk of heart disease."35

The appellate court stated, however, in affirming the FTC order, that respondent "has made statements denying the existence of scientific evidence which the record clearly shows does exist."<sup>36</sup> Accordingly, the advertiser was ordered to cease representing falsely that there is or is not scientific evidence on the relationship between eggs and various health matters.<sup>37</sup> It was also forbidden from making representations about such relationships "unless it is clearly and conspicuously disclosed in immediate conjunction therewith that there is a controversy among medical experts . . . and that respondents are presenting their side of that controversy."<sup>38</sup>

In 1977 two cases involving claims about television sets resulted in typical provisions against "Cited Proof Misrepresentations."<sup>39</sup> The same occurred in later cases.<sup>40</sup>

#### 2. Establishment Representation Cases

In the 1980's the "Cited Proof Misrepresentation" acquired its greatest fame in several analgesics cases, where it was called the "establishment representation." That term has not been used generally herein because the treatment of such claims began much earlier.<sup>41</sup> The term "establishment" stresses the need to prove the truth of a claim to a degree that satisfies the relevant scientific or medical community. However, it is not unreasonable to see the same standard of proof implied in all orders involving "Demonstrated" or "Cited Proof Misrepresentations."

Order provisions for American Home Products, Bristol-Myers, and Sterling Drug were as follows, with the material in brackets absent in Sterling:

cease and desist from: . . .

[m]aking any representation, directly or by implication, that a claim concern-

37. Egg Nutrition, 92 F.T.C. at 848.

<sup>35.</sup> Id. at 181.

<sup>36.</sup> NCEN, 570 F.2d at 161 (quoting F.T.C. v. Nat'l Comm'n on Egg Nutrition, 517 F.2d 485, 489 (7th Cir. 1975)).

<sup>38.</sup> Id. at 849.

<sup>39.</sup> Matsushita Elec. Corp. of Am., 89 F.T.C. 157, 161 (1977); General Elec. Co., 89 F.T.C. 209, 217 (1977) (involved only surveys, but provision mentioned tests) (both consent).

<sup>40.</sup> J. Walter Thompson Co., 94 F.T.C. 331, 338 (1979) (same provision, but with emphasis here on phrase "referring to"); Dancer-Fitzgerald-Sample, Inc., 96 F.T.C. 1, 14 (1980); Champion Home Builders, 101 F.T.C. 316, 324 (1983); North Am. Philips Corp., 101 F.T.C. 359, 365 (1983); McCaffrey & McCall, Inc., 101 F.T.C. 367, 369 (1983) (agency for Philips); California-Texas Oil Co., 104 F.T.C. 268, 278 (1984) (all consent).

<sup>41.</sup> The term "establish" means nothing more than "proven." American Home Prods., 98 F.T.C. 136, 374 (1981). No ads actually used the term "establish," but that was declared immaterial in light of the terms actually used, including "proves," "substantiates," "shows," and "beyond a doubt." *Id*.

ing the superior effectiveness [or superior freedom from side effects] of such product has been established or proven unless such representation has been established by two or more adequate and well-controlled clinical investigations, conducted by independent experts qualified by training and experience to evaluate the comparative effectiveness [or comparative freedom from side effects] of the drugs involved, on the basis of which it could fairly and responsibly be concluded by such experts (1) that the drug will have the comparative effectiveness [or freedom from side effects] that it is represented to have, and (2) that such comparative effectiveness [or freedom from side effects] is demonstrated by methods of statistical analysis, and with levels of confidence, that are generally recognized by such experts.<sup>42</sup>

#### In addition, Sterling was ordered to cease:

making any representation, directly or by implication, that the superior freshness, purity, stability, or speed of disintegration of such product has been established, demonstrated, or proven unless at the time such representation is made, respondent possesses and relies upon competent and reliable scientific evidence which would permit qualified experts to conclude that the product has the comparative pharmaceutical qualities it is represented to have.<sup>43</sup>

The type of proof required for the first of these provisions was discussed in the earliest of the cases, *American Home Products*:

The record reflects no real dispute as to the type of evidence scientists require before they regard it as having been proven (established) that one drug is more effective than another . . . [I]t is clear that at least since the early 1950's well-controlled clinical testing . . . have [sic] been required to establish or prove absolute or relative drug efficacy.<sup>44</sup>

A follow-up comment in *Bristol-Myers* was that "we . . . find no reason to alter the decision we reached in *American Home Products* regarding the sort of evidence necessary to substantiate a claim of established superiority for analgesics."<sup>45</sup> In *Sterling Drug*, the stated rationale was the same, with citations to *American Home Products* and *Bristol-Myers*.<sup>46</sup>

43. Sterling Drug, Inc., 102 F.T.C. at 804.

44. American Home Prods., 98 F.T.C. at 376. The appellate court approved, reasoning that the regulatory climate created by the government encourages consumers to expect such high standards. American Home Prods., 695 F.2d at 698. It cited the F.T.C. approvingly for asserting that "consumers reasonably assume that the proper governmental authorities will take steps to ensure that unqualified claims of a drug's superiority are supported by whatever proof the appropriate medical or scientific experts consider sufficient." Id.

45. Bristol-Myers, 102 F.T.C. at 332. Precedents seen earlier in this section were cited. See id. The point was affirmed. Bristol-Myers, 738 F.2d at 558.

46. Sterling Drug, 102 F.T.C. at 747. The appellate opinion affirmed this point. Sterling Drug, 741 F.2d at 1153.

<sup>42.</sup> American Home Prods., 98 F.T.C. 136 (1981), modified, American Home Prods. Corp. v. F.T.C., 695 F.2d 681 (3d Cir. 1982), modified order, 101 F.T.C. 698, 698 (1983), modified order, 103 F.T.C. 57 (1984), modified order, 103 F.T.C. 528 (1984); Bristol-Myers Co., 102 F.T.C. 21, 390 (1983), affirmed, Bristol-Myers v. F.T.C., 738 F.2d 554 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985); Sterling Drug, 102 F.T.C. 395, 802 (1983), affirmed, 741 F.2d 1146 (9th Cir. 1984), cert. denied, 470 U.S. 1084 (1985).

In a later analgesics case a "Cited Proof Misrepresentation" was also found, but the opinion stated that:

Our analysis here does not employ the term 'establishment claim' to avoid creating the impression that claims for an advertiser's possession of scientific proof will be treated by us as a unique category of claims. There is no conceptual or practical reason to single out such claims for special treatment. They are but one example of an express or implied claim that an advertiser possesses a particular level of substantiation.<sup>47</sup>

The *Thompson Medical* provision thus is cited in section VI rather than here. The required substantiation is the same, however, which may mean that in the future the categories described in this article will be consolidated.

#### 3. Substantial Question Cases

Certain misrepresentations are unusual for presenting the proof claim without explicit or implicit indicia. In the analgesics cases, the "establishment representation" was conveyed through what were called "affirmative indicia of 'proof.'"<sup>48</sup> These indicia included explicit expressions.<sup>49</sup> They also included implicit verbal claims such as descriptions of test controls or references to doctors' formulas, as well as nonverbal visual depictions of technical graphs, chemical formulas, or medical literature. All were held to add to the consumer's belief that the claim was proved to the satisfaction of the scientific or medical community.<sup>50</sup>

It was also determined, however, that when an analgesic is claimed to be superior, consumers may reasonably understand it to be established in the scientific community even though the ads are "unembellished with specific references to underlying scientific proof or tests, or other clear indicia of scientific or medical evidence (graphs, charts, treatises, etc.)."<sup>51</sup> The result was the following order provision in addition to the one cited earlier in this section, i.e., to cease and desist from:

[m]aking any representation, directly or by implication, of superior effectiveness or freedom from side effects of such product unless:

1. The superior effectiveness or superior freedom from side effects so represented has been established according to the terms set forth . . . [i.e., in the AHP provision cited earlier in this section], or

2. Each advertisement containing such representation contains a clear and conspicuous disclosure that there is a substantial question about the validity of the comparative efficacy or side effects claim, or that the claim has not been proven. Such a disclosure may consist of a clear and conspicuous statement

<sup>47.</sup> Thompson Medical Co., Inc., 104 F.T.C. 648, 822 n. 59 (1984), affirmed, Thompson Medical Co. v. F.T.C., 791 F.2d 189 (D.C. Cir. 1986). For resulting provision see *infra* text accompanying note 126.

<sup>48.</sup> American Home Prods., 98 F.T.C. at 392.

<sup>49.</sup> See supra note 41 for examples.

<sup>50.</sup> American Home Prods., 98 F.T.C. at 374-75.

<sup>51.</sup> Id. at 385. The appellate court supported the conclusion. American Home Prods., 695 F.2d at 696-97.

that the claim is 'open to substantial question,' or that the claim 'has not been proven.' If other language is used by respondent to convey the required message, respondent shall maintain . . . records sufficient to demonstrate that the required message is effectively conveyed to the advertisement's intended audience.  $^{52}$ 

The second part of this order was described as the "substantial question" issue.<sup>53</sup> When an ad makes a proof claim through "affirmative indicia," the order gives the advertiser no alternative to establishing it by the specified testing. But, for ads that prompt consumers to believe the claim, even though no "affirmative indicia" of establishment are presented, the advertiser is offered the alternative of disclosing in the advertising that there is a substantial question about the claim's validity.<sup>54</sup>

Commissioner Clanton dissented on the substantial question issue, because he disagreed that any comparative performance claim would automatically create the consumer belief of establishment. No evidence, he said, existed for such an assumption. He would have ordered AHP merely to satisfy a reasonable basis requirement less rigorous than the two-test requirement.<sup>55</sup>

Later, changes in the makeup of the FTC turned Clanton's dissent into a majority opinion. Accordingly, provisions in *Bristol-Myers* and *Sterling Drug* that might have followed *American Home Products* were written to require only a reasonable basis, which could be, but would not have to be, clinical tests. They are identified in Section VII. The FTC reopened *American Home Products* and decided it essentially in the same manner.<sup>56</sup>

53. American Home Prods., 98 F.T.C. at 385.

54. The "substantial question" ruling was not decided as a question of a reasonable basis, even though the Commission characterized it as a logical elaboration of the reasonable basis idea. *American Home Prods.*, 695 F.2d at 694, 695 n. 22.

55. American Home Prods., 98 F.T.C. at 417-23.

56. This was done by removing the provision cited supra, text accompanying note 52, and substituting the following:

cease and desist from . . . making any therapeutic performance or freedom from side effects claim for such product unless respondent possesses a reason-

<sup>52.</sup> American Home Prods. Corp., 101 F.T.C. 698, 700 (1983). For AHP's agency, Clyne Co., the parallel provision states to cease and desist from the following:

B. Making any representation, directly or by implication, of superior freedom from side effects of such product, unless: 1. Respondent knows or has reason to believe that the superior freedom from side effects so represented has been established according to the terms set forth . . . [i.e., the AHP provision cited earlier in this section], or 2. . . . [same as just stated for AHP].

Id. at 702. For Sterling's agency a similar provision was written in a consent order entered much earlier, to be rendered valid only when and if such a provision was written into *Sterling Drug*, *Inc. Sterling Drug*, 102 F.T.C. at 804; Dancer-Fitzgerald-Sample, Inc., 96 F.T.C. 1, 15, 16 (1980).

In discussing the change, *Bristol-Myers* emphasized the Commission's resolve to "hold the advertiser to the level of evidence required to convince the relevant scientific community of the claim's truthfulness only when the advertisement expressly or implicitly represents that the claim's truth has been scientifically established."<sup>57</sup> This in itself was no different; the difference, rather, was that the new majority now felt a bare claim of superior effectiveness did *not* imply establishment to consumers. It backed away from the earlier finding in *American Home Products*, observing that "there has never been any evidence to confirm this somewhat counter-intuitive reading of consumer expectations."<sup>58</sup>

Commissioners Pertschuk and Bailey dissented, Pertschuk observing that "[t]he absence of extrinsic evidence about consumer expectations has never barred the Commission from making informed, considered judgments about what consumers could reasonably be expected to believe about a given claim."<sup>59</sup> He added that the decisions involving consumer expectations about ads that do contain references to establishment were made with no greater degree of proof. To require nothing but a reasonable basis might create a situation in which competitors each have a reasonable basis for their conflicting claims, which would create a "substantial question" yet provide no disclosure.<sup>60</sup>

Bailey's dissent<sup>61</sup> discussed how critical the factual findings would be, under the new majority, as to whether the claim of establishment was represented to consumers. She gave examples to illustrate the fine line that would exist. One was that depiction of a computer typewriter would not constitute such a representation by itself, but could do so if accompanied by certain text. She concluded that finding facts would now become very difficult.<sup>62</sup>

61. Id.

able basis for making that claim. A reasonable basis for such a claim shall consist of competent and reliable scientific evidence supporting that claim. Well-controlled clinical tests conducted in accordance with the criteria set forth . . . shall be deemed to constitute a reasonable basis for a claim.

American Home Prods., 103 F.T.C. at 529-30. No change was made for the Clyne provision cited supra note 52. Reference to the "substantial question" written into Dancer was rendered invalid by its own terms when no similar provision was written into Sterling. Dancer, 96 F.T.C. at 16.

<sup>57.</sup> Bristol-Myers Co., 102 F.T.C. 21, 318 (1983).

<sup>58.</sup> Id. at 350-51. Sterling offered similar conclusions, with reference to the reasons given in Bristol. Sterling Drug, Inc., 102 F.T.C. 395, 777 (1983). Bristol added that "in some future case, a proper showing might be made that consumers did expect unequivocal scientific proof even when the advertisements made no express or implied reference to such proof." Bristol-Myers, 102 F.T.C. at 351. But here the evidence on consumers' expectations was not sufficient. Id.

<sup>59.</sup> Id. at 384.

<sup>60.</sup> Id. at 386.

<sup>62.</sup> Research on consumer perceptions of ad claims was not introduced in any of these cases, but Bailey appeared to imply that it would have to be in the future. It

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The "substantial question" issue appears dead in the form it took in the analgesics cases. However, the *Egg Nutrition* case keeps the issue alive with its provision calling for disclosure that a controversy exists among medical experts and that respondents' claims represent only one side.<sup>63</sup>

4. "Cited Proof Misrepresentation" Charged or Found But Not Specifically Prohibited

There have been consent cases in which the "Cited Proof Misrepresentation" was charged, or litigated cases in which it was found, but in which no order provision forbade it specifically. For each there were provisions of other sorts identified in later sections of this article.<sup>64</sup> They serve to prohibit the misrepresentation, but omit specific

63. See supra text accompanying note 38. The rationale was that:

Respondents object . . . to that portion of the law judge's proposed order . . . which requires that they possess a reasonable basis, consisting of competent and reliable scientific studies, for any claim that eating eggs will not increase the risk of heart disease. They contend that the difficulty of determining what constitutes adequate substantiation for the claim will prevent them from making any assertions on this subject whatsoever.

National Commission on Egg Nutrition, 88 F.T.C. 89, 192 (1976). Therefore: The simple solution to this deception, we believe, is for respondents to indicate clearly and conspicuously in their advertising that the claim they seek to make for eggs is subject to substantial disagreement by qualified experts within the scientific community. . . [W]ere the Commission to maintain a narrow view of what constitutes a 'reasonable basis' for respondents' position and require that as a condition for its expression, it might indeed come at the expense of respondents' ability to publicize new developments in the field. On the other hand, were the Commission to adopt a more expansive view of 'reasonable basis,' it would be granting *carte blanche* to respondents to assure consumers directly or by implication that egg consumption is safe, without mention of the substantial contrary opinion.

Id. at 193-94. See also cases with certain similarities, discussed *infra* as contradictory or inconsistent claims, in Section X.

64. Litigated cases: John Treadwell, 106 F.T.C. 163 (1985); Thompson Medical Co., Inc., 104 F.T.C. 648 (1984); Cliffdale Ass'n, Inc., 103 F.T.C. 110 (1984); Porter & Dietsch, Inc., 95 F.T.C. 806 (1980); Firestone Tire & Rubber Co., 81 F.T.C. 398 (1972).

Consent cases: Ogilvy & Mather Int'l, Inc., 101 F.T.C. 1 (1983) (agency for Thompson Medical); Ball-Matic Corp., 98 F.T.C. 836 (1981); Great N. Am. Indus., Inc., 98 F.T.C. 817 (1981); Standard Brands, Inc., 97 F.T.C. 233 (1981); Ted Bates & Co., 97 F.T.C. 220

would not be important for the explicit indicia of establishment, such as the word "proves," which would be assumed to create a claim of proof. Nor would it be important for a bare claim of superiority or other performance, because such claim would now as a matter of law convey no implication of establishment (a point, however, on which communication and behavior researchers might disagree—see discussion, *supra* note 3). Research would be recognized as critical, however, in dealing with those indicia, including visual and other nonverbal content, plus verbal content making indirect expressions, that might possibly be taken to imply establishment. *Bristol-Myers*, 102 F.T.C. at 386-89.

reference to it.<sup>65</sup> Of the four litigated cases, only *Thompson Medical* discusses the discrepancy.<sup>66</sup> The apparent rationale is that a provision forbidding claims unless supported by the cited tests (see Section VI) will automatically forbid misrepresentations that those tests constitute proof. Thus, the result will not differ.

Despite that seemingly reasonable rationale, numerous advertisers have received provisions identifying the "Cited Proof Misrepresentation" specifically. Perhaps the real question is why *that* has been done. A possible reason is that such cases, except for the very early *Foley*,<sup>67</sup> came after identification of the "Demonstrated Proof Misrepresentation," which had made the FTC sensitive to the specific issue

65. The situation is similar to that discussed for the "Demonstrated Proof Misrepresentation." Supra text accompanying notes 21-22.

66. Thompson Medical Co., Inc., 104 F.T.C. 648 (1984); see supra note 47 and accompanying text. The ads used such terms as "controlled clinical test," and the decision held that "we find it reasonable for consumers to expect that the claims... would be substantiated in a manner acceptable to the medical scientific community." Thompson Medical, 104 F.T.C. at 814.

In Porter & Dietsch the complaint did not charge a "Cited Proof Misrepresentation," and this may be why it was not prohibited specifically in the order. Still, the finding was made that the advertisers "not only implied the existence of substantiation but they also represented that this substantiation consisted of competent scientific proof." *Porter & Dietsch*, 95 F.T.C. at 865. See also Porter & Dietsch, Inc. v. F.T.C., 605 F.2d 294, 302 (7th Cir. 1979).

In *Cliffdale* the ads used such terms as "tested and proven," "field tests," and "lab tests," and the decision held that "[t]hese advertisements can be reasonably understood to imply that competent scientific tests support the performance claims." *Cliffdale*, 103 F.T.C. at 169.

67. 48 F.T.C. 670 (1952).

<sup>(1981) (</sup>agency for Standard Brands); Sorga, Inc., 97 F.T.C. 205 (1981) (agency for American Home Products); American Home Prods. Corp., 95 F.T.C. 884 (1980); Mid City Chevrolet, Inc., 95 F.T.C. 371 (1980); Harvey Glass, M.D., 95 F.T.C. 246 (1980); San-Mar Laboratories, Inc. 95 F.T.C. 236 (1980); The Nat'l Media Group, Inc., 94 F.T.C. 1096 (1979); Karr Preventative Medical Prod., Inc., 94 F.T.C. 1080 (1979); C.I. Energy Dev., Inc., 94 F.T.C. 1337 (1979); RR Int'l, Inc., 94 F.T.C. 1312 (1979); Leroy Gordon Cooper, Inc., 94 F.T.C. 674 (1979); Admarketing, Inc., 94 F.T.C. 664 (1979) (agency for Cooper); American Consumer, Inc., 94 F.T.C. 648 (1979); Ford Motor Co., 93 F.T.C. 873 (1979); Savoy Drug & Chem. Co., 86 F.T.C. 957 (1975); Hugh Mooney t/a Organic Masque Co., 85 F.T.C. 507 (1975); General Motors Corp., 84 F.T.C. 653 (1974); Mota-Nu, Inc., 83 F.T.C. 1467 (1974); PPG Indus., Inc., 80 F.T.C. 53 (1972).

The Commission in *Firestone* alluded to the discrepancy, noting that "[r]espondent agrees that its advertisement represents that its 25 percent quicker stopping claim has been substantiated by adequate scientific tests." *Firestone*, 81 F.T.C. at 450. The appellate court agreed that this was implied to consumers. Firestone Tire & Rubber Co. v. F.T.C., 481 F.2d 246, 251 (6th Cir. 1973), *cert. denied*, 414 U.S. 1112 (1973). Yet, the order provision did not specifically forbid a proof misrepresentation. Perhaps the reason is that the hearing examiner refused to find that tests had been represented to exist. *Firestone*, 81 F.T.C. at 407. He wrote an order accordingly. *Id.* at 427-28. The Commission later disagreed with him on that point. *Id.* at 444, 450. However, the factual finding to which the Commission gave most attention was that the accompanying product claim was unsupported. The examiner's proposed provision forbade the claim unless supported, and the Commission's final order left it substantially unchanged. *Id.* at 475. Apparently it saw no need to change it to forbid the "Cited Proof Misrepresentation" specifically.

of proof. It was only later that formulations were developed (see Sections VI-VII) which included proof misrepresentations within provisions aimed at misrepresentations more widely. A current rationale for maintaining separate identification of the "Cited Proof Misrepresentation" exists in the analgesics decisions in which the FTC decided that proof claims should be subjected to a higher level of substantiation than claims misrepresented merely as true. Such a distinction serves at present to keep the "Cited Proof Misrepresentation" alive as a specific category.

#### B. Surveys

American Tire was ordered to cease "representing... that respondents have, through an independent survey, or in any other manner, determined the prices being charged, in the trade area in which the representation is made, for merchandise ... unless respondents ... have determined ... that the identical merchandise is being sold ... at the represented prices."<sup>68</sup>

General Electric was ordered to:

cease and desist from . . . [a]dvertising or offering such product(s) for sale by referring to any test, experiment, demonstration, study or survey, or any or all of the results thereof (hereafter "evidence"), which evidence is represented, either directly or by implication, as supporting, showing or proving . . . the existence or nature of any fact or product feature respecting such product(s) when such evidence does not support, show or prove such fact or product feature . . . . <sup>69</sup>

A number of cases were similar to those discussed under the tests discussed above, in that the "Cited Proof Misrepresentation" was charged or found, but the resulting provisions (see Sections VI-VIII) made no specific reference to it.<sup>70</sup> No rationales were offered.<sup>71</sup>

Additional cases mentioned surveys as an apparent throw-in, because the challenged representations involved only tests: Ford Motor Co., 93 F.T.C. 873 (1979); American Consumer, Inc., 94 F.T.C. 648 (1979); Admarketing, Inc., 94 F.T.C. 664 (1979) (agency for Cooper); Leroy Gordon Cooper, Inc., 94 F.T.C. 674 (1979); RR Int'l, Inc., 94 F.T.C. 1312 (1979); C.I. Energy Development, Inc., 94 F.T.C. 1337 (1979); Mid City Chevrolet,

<sup>68.</sup> American Tire Co., 77 F.T.C. 1169, 1176 (1970) (consent).

<sup>69.</sup> General Elec. Co., 89 F.T.C. 209, 217 (1977) (consent). The provision mentions tests, but the misrepresentations involved only surveys. Thompson, as agency for Sears, was given a similar provision, even though Sears, after litigation, was not. See supra notes 20, 21 and accompanying text. The application to surveys was apparently a throw-in, because the advertising involved no reference to surveys.

<sup>70.</sup> Consent cases: J. Walter Thompson Co., 97 F.T.C. 333 (1981) (agency for Teledyne); Teledyne Inc., 97 F.T.C. 320 (1981); Standard Brands, Inc., 97 F.T.C. 233 (1981); Ted Bates & Co., 97 F.T.C. 220 (1981) (agency for Standard Brands). Litigated cases: American Home Prods. Corp., 95 F.T.C. 884 (1980); The Kroger Co., 100 F.T.C. 573 (1982); Litton Indus., Inc., 97 F.T.C. 1 (1981).

#### C. Summary

Advertisers who commit "Cited Proof Misrepresentations" have frequently been ordered specifically to cease them unless tests or surveys of the type cited substantiate the accompanying claims. Such specific orders are very likely to occur in those cases that also include provisions involving lesser references to tests which may be substantiated by lesser standards. In some cases involving "Cited Proof Misrepresentations," the orders do not mention such misrepresentations specifically.

#### IV. THE CITED EVIDENCE MISREPRESENTATION

Whereas, the first two categories involve claims that tests or surveys *prove* accompanying claims, the "Cited Evidence Misrepresentation" involves the lesser claim that tests or surveys exist as support. Gurley Industries was ordered to:

cease and desist from . . . [r]epresenting . . . that respondents' spark plugs or any other products have been tested unless such spark plugs or other products have in fact been subjected to such tests and testing procedures as will establish that each spark plug or other item will fully perform in the manner and to the extent . . . represented.<sup>72</sup>

General Motors, after false claims of EPA tests of Cadillac's gasoline mileage, was banned from:

Representing... by reference to a test or tests, that the performance of any automobile has been tested either alone or in comparison with other automobiles unless such representation(s) accurately reflect the test results and unless the tests themselves are so devised and conducted as to substantiate each such representation concerning the featured tests.<sup>73</sup>

Mooney and Savoy were ordered to "cease and desist from . . . disseminating . . . any advertising . . . which misrepresents . . . the extent to which any such product has been tested, or the results of its use demonstrated."<sup>74</sup>

72. Gurley Indus., Inc. 77 F.T.C. 477, 483-84 (1970) (consent).

73. General Motors Corp., 84 F.T.C. 653, 660 (1974) (consent).

74. Hugh Mooney t/a Organic Masque Co., 85 F.T.C. 507, 510-11 (1975); Savoy Drug & Chem. Co., 86 F.T.C. 957, 961 (1975) (both consent). The term "demonstrated" appears in the context to mean only "displayed," not "proved." Similarly, advertisers of acne preparations were ordered to "cease and desist from . . . [d]isseminating . . . any advertisement . . . which . . . [m]isrepresents the extent to which any product has been tested or the results of any such test(s)." Cooga Mooga, Inc., 92 F.T.C. 310, 319 (1978), modified, 98 F.T.C. 814 (1981) (no change involving tests); Karr Preventative Medical

Inc., 95 F.T.C. 371 (1980); Great N. Am. Indus., Inc., 98 F.T.C. 817 (1981); Ball-Matic Corp., Inc., 98 F.T.C. 836 (1981); Cliffdale Assoc., 103 F.T.C. 110 (1984).

<sup>71.</sup> Litton suggested the F.T.C. had come close to specifically prohibiting a "Cited Proof Misrepresentation," after concluding that Litton represented the survey preferences of servicing technicians as establishing that Litton's microwave ovens were superior. Litton, 97 F.T.C. at 18. The reason for not doing so may have been because of the finding that the preferences were not as claimed in the first place, which was a reason parallel to that noted for *Firestone*. See Firestone Tire & Rubber Co., 81 F.T.C. 398 (1972) and supra note 66.

The remaining cases have provisions referring to both tests and surveys, although the misrepresentations did not involve both. Ford<sup>75</sup> was given the same provision as General Motors after failing to disclose its lack of evidence that its advertised test conditions, on which its mileage claims were based, approximated or equaled the conditions an ordinary driver would face. Ford had used tests of its own devising.

Standard Brands, along with its agency, Ted Bates, was charged with misrepresenting that surveys showed that doctors recommended Fleischmann's margarine. They were ordered to:

This type of misrepresentation has been infrequent because mentions of tests or surveys usually have resulted in charges of proof misrepresentation. Only two of the cases just discussed, *Gurley* and *Cooga Mooga*, actually involved charges of the Cited Evidence Misrepresentation. The others except for *AHC Pharmacal* involved charges of the "Cited Proof Misrepresentation," which resulted in provisions not mentioning that misrepresentation specifically.<sup>77</sup>

76. Standard Brands, Inc., 97 F.T.C. at 233, 242 (1981); Ted Bates & Co., 97 F.T.C. 220, 229 (1981). The material in brackets appears in *Bates* only. The section headed by "(c)" is discussed in Section X, *infra* note 342. The misrepresentations involved no tests.

Prods., Inc., 94 F.T.C. 1080, 1090 (1979); The Nat'l Media Group, 94 F.T.C. 1096, 1107 (1979); AHC Pharmacal, Inc., 95 F.T.C. 528, 534 (1980), *modified*, 101 F.T.C. 40 (1983) (no modification of this provision). The following had virtually identical provisions: San-Mar Laboratories, Inc., 95 F.T.C. 236, 241-42 (1980); Harvey Glass, M.D., 95 F.T.C. 246, 253 (1980). See also John Treadwell, 106 F.T.C. 163, 170 (1985). All were consent cases.

<sup>75.</sup> Ford Motor Co., 87 F.T.C. 756 (1976) (partial order and remand), 93 F.T.C. 873, 881 (1979) (consent). The order defined tests as including surveys, although the case involved no surveys.

<sup>77.</sup> General Motors Corp., 84 F.T.C. 653 (1974); Hugh Mooney, t/a Organic Masque Co., 85 F.T.C. 507 (1975); Savoy Drug & Chem. Co., 86 F.T.C. 957 (1975); Ford Motor Co., 93 F.T.C. 873 (1979); Karr Preventative Medical Prods., Inc., 94 F.T.C. 1080 (1979); The Nat'l Media Group, Inc., 94 F.T.C. 1096 (1979); San-Mar Laboratories, Inc., 95 F.T.C. 236 (1980); Harvey Glass, M.D., 95 F.T.C. 246 (1980), Ted Bates & Co., 97 F.T.C. 220 (1981); Standard Brands, Inc., 97 F.T.C. 233 (1981); John Treadwell, 106 F.T.C. 163 (1985). AHC Pharmacal, Inc., 95 F.T.C. 528, 534 (1980), had no complaint charge involving tests. All are consent cases, which offer no explanation. See explanation in text at notes 22, 65.

## V. THE REASONABLE BASIS/SUBSTANTIATION (RB/S) MISREPRESENTATION

The categories discussed thus far involve misrepresentations stated explicitly, albeit sometimes indirectly by related terminology or by nonverbal means. By contrast, the "Reasonable Basis/Substantiation (RB/S) Misrepresentation" occurs in ads that make no references, explicit or implicit, to tests or surveys, but which, according to the FTC, imply to consumers that a reasonable basis or substantiation for the claims existed prior to the claims' dissemination.

Prior to Sections VI-VIII, in which the RB/S order provisions are identified, this section explains the rationale for combining reasonable basis orders and substantiation orders. It also explains other combinatorial decisions used here. A reader's caveat is that this article, although exhaustive with respect to tests and surveys in FTC cases, does *not* attempt to be exhaustive with respect to all RB/S cases. Order provisions that call for a reasonable basis for substantiation and yet require nothing interpretable as tests or test-like, surveys or survey-like, are not within the topic treated here.<sup>78</sup> More theoretical discussions of the reasonable basis or substantiation principles are not treated here either.<sup>79</sup>

Another type of case not treated here is illustrated by *Warner-Lambert*, in which the Commission said, "[w]e must conclude that the preponderance of the evidence demonstrates that . . . Listerine . . . will not prevent or cure colds or sore throats or ameliorate cold symptoms." Warner-Lambert Co., 86 F.T.C. at 1398, 1496-97 (1975)(footnote omitted). In such instances the prohibition of the claim is made outright. No RB/S (and so, no tests or surveys) can be considered because the F.T.C. concludes none can ever exist.

<sup>78.</sup> Several cases contain at least one provision that so interprets the RB/S along with at least one that does not: General Elec. Co., 89 F.T.C. 209, 219 (1977); Cooga Mooga Inc., 92 F.T.C. 310, 320 (1978); Karr Preventative Medical Prods., Inc., 94 F.T.C. 1080, 1092 (1979); The Nat'l Media Group, Inc., 94 F.T.C. 1096, 1108 (1979); San-Mar Laboratories, Inc., 95 F.T.C. 236, 243 (1980); Harvey Glass, M.D., 95 F.T.C. 246, 253 (1980); Hayoun Cosmetique, Inc., 95 F.T.C. 794, 801 (1980); Universal Bodybuilding, Inc., 96 F.T.C. 783, 791-92 (1980); Ogilvy & Mather Int'l, Inc., 101 F.T.C. 1, 14-15 (1983) (agency for Thompson Medical); AHC Pharmacal, Inc., 95 F.T.C. 528, 534-35 (1980). As all were consent cases, no explanation is available for requiring the RB/S without specification. Perhaps those provisions requiring the RB/S without specification were regarded by their authors as less essential than those dealing with the specific misrepresentations found.

<sup>79.</sup> But see, Note, Pfizer Reasonable Basis Test — Fast Relief for Consumers But a Headache for Advertisers, 1973 DUKE L.J. 563 (1973); Note, Unfairness in Advertising: Pfizer, Inc., 59 VA. L. REV. 324 (1973); Note, The F.T.C. Advertising Substantiation Program, 61 GEO. L.J. 1427 (1973); R. POSNER, REGULATION OF ADVERTISING BY THE F.T.C. (1973); Williams, Through the Looking Glass—The FTC's Advertising Substantiation Exclusionary Rule, 27 AM. U.L. REV. 76 (1977); J. Healey, The F.T.C. Advertising Substantiation Program and Changes in the Content of Advertising in Selected Industries (1978) (unpublished Ph.D thesis in F.T.C. library); Cohen, The F.T.C's Advertising, supra note 1; Scammon and Seminik, The FTC's "Reasonable Basis" for Substantiation of Advertising: Expanded Standards and Implications, 12 J. ADVERTISING 4 (No. 1, 1983); Handler, supra note 2.

## A. Combining Reasonable Basis and Substantiation Misrepresentations

The concept of the "RB/S Misrepresentation" combines two categories used by the FTC: (1) the advertising claim that falsely implies the existence of a reasonable basis for the claim; and (2) the false advertising claim that is required to have substantiation. The existence of separate designations implies a differentiation, and indeed the two represented differing theories originally. However, in terms of the roles subsequently played in the orders examined here, they are so alike that it seems counterproductive to treat them separately.<sup>80</sup> The assumption, therefore, is adopted that the difference in terminology represents no significant difference in substance for present purposes. That assumption is based on the following analysis of the two concepts, beginning with the case in which the term "reasonable basis" first appeared alongside the earlier "substantiation."<sup>81</sup>

The *Pfizer* complaint did not use the phrase "reasonable basis;" rather, it charged a lack of substantiation.<sup>82</sup> The opinion, however, called it an "unfair practice . . . to make an affirmative product claim without a reasonable basis for making that claim."<sup>83</sup> Thus, the term was born as an interpolation into a matter introduced as involving substantiation.

*Firestone*, reported only two months later, cited *Pfizer* in declaring that claims failed to be supported by a reasonable basis.<sup>84</sup> The order, however, did not require a reasonable basis specifically, perhaps because the commissioners contented themselves with altering rather than rewriting the initial decision's order.<sup>85</sup> The initial decision had

85. Id. at 428, 475.

<sup>80.</sup> Pfizer, Inc., 81 F.T.C. 23 (1972), grounded the reasonable basis violation in unfairness in contrast to the substantiation concept's grounding in deceptiveness. Shortly thereafter, however, in *National Dynamics*, the reasonable basis concept was grounded as well in deceptiveness. National Dynamics Corp., 82 F.T.C. 488, 550 (1973); see also *id.* at 550 n.10. No subsequent reasonable basis provision cited in this article was grounded exclusively in unfairness (i.e., without also being grounded simultaneously in deceptiveness), and many were grounded only in deceptiveness.

<sup>81.</sup> Pfizer, Inc., 81 F.T.C. 23 (1972) (dismissed).

<sup>82.</sup> Id. at 25. The complaint included a standard that eventually became central to the reasonable basis concept: that a claim should be called unfair if there is lacking any basis for believing it prior to the time of its first dissemination. This idea of a *prior* basis was not controversial for explicit mentions of tests or surveys, because the explicit mention made clear that they *were* being represented to have existed prior to the advertising. But, in cases involving no explicit representations about tests or surveys, the matter of implying prior existence became a key issue.

<sup>83.</sup> Id. at 62; see also id. at 64.

<sup>84.</sup> Firestone Tire and Rubber Co., 81 F.T.C. 398, 463 (1972).

been published prior to *Pfizer*. Thus the *Firestone* opinion, although it incorporated the reasonable basis thinking, ordered that claims be "substantiated by competent scientific tests."<sup>86</sup>

The interweaving of terms occurred further in 1973: "We have held that the test applied to determine the adequacy of substantiation is whether or not it provides respondents with a reasonable basis for believing their claims are true."<sup>87</sup> And in *Ford* and *J. Walter Thompson* in 1974, each order used one of the concepts in one provision and the other in another.<sup>88</sup> Also in 1974, provisions otherwise the same called for Standard Oil of California to provide substantiation and for its agency, BBD&O, to provide a reasonable basis.<sup>89</sup>

After the Crown Central opinion said "[w]e conclude that competent test evidence is necessary to provide the required reasonable basis,"<sup>90</sup> it then proceeded to require substantiation and not a reasonable basis.<sup>91</sup> A possible determinant was that the complaint, written in 1971, charged only deception whereas the reasonable basis concept originated under unfairness. Many later complaints routinely charged both deception and unfairness. Still, there were cases in which complaints charged a lack of a reasonable basis but orders required substantiation.<sup>92</sup> Recent orders have been more prone to require a reasonable basis.

Perhaps the best evidence of interchangeability is seen in provisions that blend the two terms to create, in effect, a "reasonable basis that substantiates."<sup>93</sup> Consistent with this frequent blending, no discussion in any case of the past decade has suggested the two concepts are different. For these reasons, the two are blended here into what is called the "RB/S Misrepresentation."

89. Standard Oil Co. of Cal., 84 F.T.C. 1401, 1490-91 (1974).

93. E.g., Union Carbide Corp., 84 F.T.C. 591, 598 (1974) (consent); Sears, Roebuck, & Co., 95 F.T.C. 406, 525 (1980).

<sup>86.</sup> Id. at 475. This altered the examiner's requirement for claims "substantiated by competent tests . . . ." Id. at 428; see also Id. at 463.

<sup>87.</sup> National Dynamics Corp., 82 F.T.C. 488, 553 (1973), modified, National Dynamics v. F.T.C., 492 F.2d 1333 (2d Cir. 1974) (modifications not affecting tests); cert. denied, 419 U.S. 993 (1974), modified, 85 F.T.C. 391 (1975), modified, 85 F.T.C. 1052 (1975).

<sup>88.</sup> Ford Motor Co., 84 F.T.C. 729 (1974); J. Walter Thompson Co., 84 F.T.C. 736 (1974) (agency for Ford) (both consent). See also, Ford Motor Co. and J. Walter Thompson Co. v. F.T.C., aff'd, 547 F.2d 954 (6th Cir. 1976), cert. denied, 431 U.S. 915 (1977).

<sup>90.</sup> Crown Cent. Petroleum Corp., 84 F.T.C. 1493, 1548 (1974), modified with explanatory Memorandum, Crown Cent. Petroleum Corp. v. F.T.C., 530 F.2d 1093 (D.C. Cir. 1976) (no published opinion), modified, 88 F.T.C. 210 (1976). For similar comments, see also Crown Cent., 84 F.T.C. at 1529, 1538.

<sup>91.</sup> Crown Cent., 88 F.T.C. at 211. The discussion of substantiation recognized the "prior" requirement: "We find that the . . . advertisements do represent that tests had been conducted prior to the publication of the ads." Crown Cent., 84 F.T.C. at 1549.

<sup>92.</sup> The first of these was Porter & Dietsch, Inc., 95 F.T.C. 806 (1980). See discussion supra text accompanying note 64.

### B. Combining RB/S Cases That Do and Do Not Explicitly Charge The RB/S

This article combines RB/S cases resulting from two kinds of complaint charges (or, in litigated cases, findings). In the first, the advertiser is specifically charged with implying deceptively that an RB/S exists for the product claim. In the other, the advertiser is charged only with the deceptive product claim. Notwithstanding their differences, the compelling reason for combining these cases is that their orders show no systematic variation; in both the advertiser is found to lack the RB/S and must cease making the claim without having one.

The reason for the similarity is the FTC's conclusion that product claims typically imply to consumers that an RB/S exists. Thus, a complaint charge of a deceptive product claim, because the claim implies the RB/S, is no different from a specific charge of a deceptive RB/S claim. The Commission's assumption of the implied RB/S was first approached in *New York Jewelry Co.*:

However, the concept in New York Jewelry Co. did not develop into the fullblown form of a principle—it was more a matter of fitting the remedy to claims made with a flagrant disregard for the truth. But, it was cited in *Pfizer*, where the principle was developed: "The consumer is entitled, as a matter of marketplace fairness, to rely upon the manufacturer to have a 'reasonable basis' for making performance claims."<sup>95</sup> In the context of *Pfizer* there was no finding of an implied reasonable basis, because the charge was of unfairness rather than deceptiveness. In *National Dynamics*, however, the missing link was added: "[W]e find [respondents] represented to consumers that

<sup>94.</sup> New York Jewelry Co., 74 F.T.C. 1361, 1411 (1968) (emphasis in original), aff'd, Tashof v. F.T.C., 437 F.2d 707 (D.C. Cir. 1970). The appellate court agreed:

Where a businessman has wrought a wrong on the public, he may be held to a reasonable business procedure that will prevent repetition of that wrong, and in view of his past record he will not be permitted to object that his own approaches might also avoid this wrong in the future ....

<sup>Tashof, 437 F.2d at 715. "This requirement shifts to [respondent] the burden of proving its innocence; and as the majority opinion concedes, might subject [respondent] to heavy civil penalties even if its advertisement is true."</sup> *Id.* at 716 (Robb, J., dissenting). 95. Pfizer, Inc., 81 F.T.C. 23, 62 (1972) (dismissed).

they had a reasonable basis for believing their claims were true."<sup>96</sup> There was an "implied representation of substantiation . . ." and it may be found deceptive.<sup>97</sup>

Accordingly, it appears that when the FTC charges deceptiveness in product claims, it is also charging a deceptive implication of an RB/S, whether or not the latter is made explicit in complaint or findings. Consequently, the discussion herein combines the two types of cases without noting the distinction.

## C. Combining RB/S Cases That Do and Do Not Charge A Specific Type of RB/S

When the FTC charges (or, in litigated cases, finds) that an RB/S is represented to consumers, the nature of the presumed RB/S is sometimes left unspecified, while at other times is said to consist of certain specific tests. *Pfizer* was the progenitor of the latter, its complaint charging that "respondent represents . . . directly or by implication, that each of the statements . . . has been substantiated by respondent by adequate and well-controlled scientific studies or tests prior to the making of such statements . . . ." and that doing so was unfair.<sup>98</sup> The charges were dismissed when the Commission concluded the specific tests were not implied.<sup>99</sup> It agreed that a reasonable basis of some sort had been implied, but that complaint counsel, merely by showing the absence of the specified type of tests, had not shown that a reasonable basis was absent.<sup>100</sup>

<sup>96.</sup> National Dynamics Corp., 82 F.T.C. 488, 549 (1973).

<sup>97.</sup> Id. at 550. See also Crown Cent. Petroleum Corp., 84 F.T.C. 1493, 1529 (1974) ("the making of such performance claims is an implied representation that there is a reasonable basis therefore."). Also, National Commission on Egg Nutrition held that: It is settled law that an advertiser in rendering an affirmative claim for a product must have a 'reasonable basis' therefor, consisting of such evidence as is appropriate to provide substantiation for the type of claim being made [with citations to Pfizer, National Dynamics, and Firestone]. . . . The justification for such a requirement is apparent. Many consumers are likely to assume that when a product claim is advanced which is in theory subject to objective verification, the party making it possesses a reasonable basis for so doing. . . . As a result, the rendition of a claim based upon inadequate or nonexistent substantiation violates Section 5 for failure to state a highly material fact, whose omission is deceptive.

National Comm'n on Egg Nutrition, 88 F.T.C. 89, 191 (1976), cited in Porter & Dietsch, Inc., 95 F.T.C. 806, 866 (1980).

Bristol-Myers argued on appeal that "the FTC is not entitled to presume that consumers expect all supportable product claims to possess a reasonable basis to support the claims." Bristol-Myers v. F.T.C., 738 F.2d 554, 562 (2d Cir. 1984). However, the contention was not explored, because the court ruled that the Commission had made a factual finding rather than a presumption. *Id*.

<sup>98.</sup> *Pfizer*, 81 F.T.C. at 24-25. This was not a "Cited Proof Misrepresentation" because the ads for Un-Burn had mentioned no tests in making their claims about the product's performance qualities.

<sup>99.</sup> Id. at 58-59.

<sup>100.</sup> Id. at 66-68.

In National Dynamics, the complaint alleged false claims that "[e]ach of the use or performance representations . . . has been substantiated by respondents through competent scientific tests or by authenticated, controlled and duly recorded user tests or both."<sup>101</sup> The Commission concluded that, although the referenced tests did not exist, a reasonable basis for making performance claims nonetheless existed.<sup>102</sup> Apparently, consumers could be expected to infer that an RB/S existed but not infer the existence of specified types of tests.

Allegations of specific test types have occurred in only two other instances.<sup>103</sup> The failures in *Pfizer* and *National Dynamics* demonstrate why alleging a specific test is rare. An implication of an RB/S consisting of precisely specified tests or surveys is considerably more difficult to prove than an implication that an RB/S exists. Consequently, the typical practice became either one of charging that an unspecific RB/S was misrepresented to exist, or merely that a product claim was misrepresented, which in turn implied that an RB/S was misrepresented to exist. For these reasons, this discussion combines the two types of cases.

## D. Distinguishing RB/S Cases By the Role Given To Tests and/or Surveys

As just discussed, various types of "RB/S Misrepresentations" are combined in Sections VI-VIII. A process or a means to distinguish these misrepresentations will now be discussed. When an RB/S of unspecified type is held implied to consumers, the FTC must determine what kind of RB/S will match consumers' expectations. Thus, where tests or surveys are implied, there have developed three general types of matching RB/S expectations. Three types exist because in the pioneer *Pfizer* case the role of tests or surveys was determined to be variable. After the Commission concluded that "Pfizer did not conduct adequate and well-controlled scientific studies or tests *prior* to marketing Un-Burn,"<sup>104</sup> it considered the separate question of whether Pfizer had no reasonable basis. The Commission concluded

<sup>101.</sup> National Dynamics Corp., 82 F.T.C. 488, 491 (1973).

<sup>102.</sup> Id. at 552-53 (with reference to Pfizer).

<sup>103.</sup> Intermatic was charged with representing that it "has a reasonable basis in valid scientific studies or tests . . ." Intermatic, 93 F.T.C. 537, 538 (1979) (consent). Universal Bodybuilding was charged with representing "that they have, and rely on, competent scientific tests or studies sufficient to provide a reasonable basis . . ." Universal Body Building, 96 F.T.C. 783, 787 (1980) (consent). These were not "Cited Proof Misrepresentations," since tests were not claimed in the ads. See infra note 112.

<sup>104.</sup> Pfizer, Inc., 81 F.T.C. 23, 66 (emphasis in original).

that the lack of adequate tests did not necessarily imply the absence of a reasonable basis. In *Pfizer*, tests were held unnecessary to the formation of a reasonable basis,<sup>105</sup> although tests might be required under other circumstances.<sup>106</sup>

The issue arose again in National Dynamics, where the complaint alleged there were no "competent scientific or valid user tests,"<sup>107</sup> and the facts did not show otherwise.<sup>108</sup> Tests were done, however, by independent laboratories which submitted reports to the respondent. The Commission concluded that the reports constituted a reasonable basis because "the record [did] not disclose respondents possessed the capacity or the scientific expertise in-house to undertake such technical evaluations. As laymen in the field of scientific evaluation, respondents . . . relied upon conclusions in the test reports as scientific statements based upon competent scientific tests . . . . "<sup>109</sup>

The immediate impact in these cases was to excuse the advertisers.<sup>110</sup> The long-term impact, however, suggests that the extent to which tests and/or surveys are required as necessary components of an acceptable RB/S may vary.

Accordingly, the next three sections cover the existing variations, arranged by the extent to which tests or surveys are demanded. Each section proffers reasons for the use of the particular variations. The recent *FTC Policy Statement Regarding Advertising Substantiation*<sup>111</sup> offers additional explanation. It notes that any objective advertising claim carries an explicit or implied representation of a reasonable basis, although not necessarily of a particular type. For those that state or imply a certain level of substantiation or specific type of support, the advertiser must provide backing for what is represented. For advertisements making no such representation, the Commission will decide what constitutes a reasonable basis. Various factors will be considered, including the type of substantiation that experts believe consumers would expect. Finally, the Commission urges that expert evidence be obtained.

The significance of the order of the provisions in Sections VI-VIII

<sup>105.</sup> Id. at 68.

<sup>106.</sup> Id. at 64.

<sup>107.</sup> National Dynamics Corp., 82 F.T.C. 488, 552 (1973).

<sup>108.</sup> Id.

<sup>109.</sup> Id. at 556.

<sup>110.</sup> *Pfizer* was dismissed because complaint counsel, by not having argued the lack of reasonableness of such things as the tests Pfizer did conduct, or of the existing medical literature or clinical experience, was found not to have met its burden of proving that a reasonable basis was lacking. In *National Dynamics* the Commission concluded a reasonable basis was *not* lacking.

<sup>111. 48</sup> Fed. Reg. 10471 (1983). 47 A.T.T.R. 234 (1984), appended to Thompson Medical Co., Inc., 104 F.T.C. 648, 839 (1984).

is their respective representations of relatively high, medium, and low burdens of compliance for advertisers in the level of scientific effort, and consequent time and expense, required. Indeed, there may be situations in which a higher level would mean the impossibility of obtaining an RB/S, regardless of the resources expended, while a lower level would create no such impediment.

#### VI. RB/S MUST BE, OR MUST INCLUDE, A TEST OR SURVEY

This section discusses order provisions which specify a test or survey as an absolute requirement for the RB/S. Only the "unless" portions of these provisions are examined. Prior to this language, the provisions typically order the advertisers to cease and desist from making various representations. The "unless" portions then specify that the advertisers may make the representations, should they acquire the specified test or survey which was previously absent.

A large number of provisions specify a test requirement without designating an exact type of test.<sup>112</sup> The following sampling illus-

<sup>112.</sup> Sunbeam Corp., No. C-3181, F.T.C. slip op. (1986); Rush-Hampton, No. 9167, F.T.C. slip op. (1985); Associated Mills, 106 F.T.C. 5, 23 (1985); Campbell-Ewald, 104 F.T.C. 511, 515 (1984) (agency for General Motors); General Motors Corp., 104 F.T.C. 511, 512 (1984); Monte Proulx, 102 F.T.C. 1722, 1726 (1983) (three provisions); Emergency Devices, Inc., 102 F.T.C. 1713, 1718 (1983) (three provisions); National Ass'n of Scuba Diving Schools, 100 F.T.C. 439, 446 (1982) (two provisions); Renuzit Home Prods. Co., 99 F.T.C. 291, 294 (1982); Boekamp, Inc., 97 F.T.C. 291, 315 (1981); Energy Efficient Sys., Inc., 97 F.T.C. 265, 286 (1981); Universal Bodybuilding, Inc., 96 F.T.C. 783, 791-92 (1980) (three provisions); Porter & Dietsch, Inc., 90 F.T.C. 770, 885 (1977), modified, Porter & Dietsch v. F.T.C., 605 F.2d 294 (7th Cir. 1979), cert. denied, 445 U.S. 950 (1980), modified order, 95 F.T.C. 806 (1980); Kettle Moraine Elec., Inc., 95 F.T.C. 398, 401 (1980); Montgomery Ward & Co., 95 F.T.C. 265, 273 (1980); C.I. Energy Dev., Inc., 94 F.T.C. 1337, 1359 (1979); RR Int'l, 94 F.T.C. 1312, 1334 (1979); Intermatic, Inc., 93 F.T.C. 537, 541 (1979); Norris Indus., Inc., 92 F.T.C. 989, 1015 (1978); Vital-E, 92 F.T.C. 880, 896 (1978); Johnson Prods. Co., Inc., 91 F.T.C. 506, 507 (1978) (two provisions); Albano Enters. Inc., 89 F.T.C. 523, 527 (1977); Revlon Inc., 89 F.T.C. 1, 10, 11, 13 (1977) (five provisions); Relco Inc., 88 F.T.C. 396, 400 (1976) (two provisions); Crown Cent. Petroleum Corp., 88 F.T.C. 210, 211 (1976); Perma-Strate Co., 87 F.T.C. 155, 161 (1976); Lustrasilk Corp. of America, 87 F.T.C. 145, 150, 151-52 (1976) (six provisions); Parker Advertising, Inc., 87 F.T.C. 68, 73 (1976) (agency for Bridgestone Tire); Bridgestone Tire Co. of America, 86 F.T.C. 825, 830 (1975); C.E.B. Prods., Inc., 85 F.T.C. 565, 575 (1975); Hugh Mooney t/a Organic Masque Co., 85 F.T.C. 507, 511 (1975); Standard Oil Co. of Cal., 84 F.T.C. 1401, 1490-91 (1974) (for each of two respondents) (Standard's agency BBD&O also a named party); Ronnie Ray's National Health Studios, 84 F.T.C. 1238, 1242 (1974); K Mart Enter. Inc., 84 F.T.C. 574, 577 (1974); Gloria Stevens, Inc., 84 F.T.C. 438, 445 (1974); Peel-O-Matique, Inc., 83 F.T.C. 1483, 1488 (1974) (two provisions); Mota-Nu, Inc., 83 F.T.C. 1467, 1470 (1974); Royal Indus., Inc., 83 F.T.C. 507, 512 (1973) (two provisions); Lear Siegler, Inc., 83 F.T.C. 503, 506 (1973); Boise Tire Co., 83 F.T.C. 21, 25 (1973); Nu Dimensions Int'l, Ltd., 81 F.T.C. 793, 804 (1972) (two provisions); Firestone Tire & Rubber Co., 81 F.T.C. 398, 475 (1972); PPG Indus., 80 F.T.C. 53,

trates the many variations in wording. Some of these variations may create significant differences in substantive meaning, while others may not; the cases provide no guidance:

unless each such quality, characteristic, capacity, result, manner of performance, or effectiveness has been fully substantiated by competent and reliable scientific testing.^{113}

unless and only to the extent that each and every such representation is true and has been fully and completely substantiated by competent scientific tests.  $^{114}$ 

unless at the time such representation is made, respondents have in their possession, and rely on, competent, reliable and well-controlled scientific tests which provide a reasonable basis to believe that the representations are truthful. $^{115}$ 

unless at the time such representation is made it is fully and completely substantiated by competent scientific or medical tests or studies, with the results  $\dots$  available in written form for inspection by the Federal Trade Commission for at least three years following the final use of the representation  $\dots$ .<sup>116</sup>

unless at the time such representation is first disseminated ... respondent has a reasonable basis for such representation, which shall consist of a competent scientific test or tests that substantiate such representation; and ... respondent's agents, employees or representatives who are responsible for engineering approval of any advertisement containing such representation rely on such test or tests in approving such advertisement and provide ... a written statement that such reasonable basis exists which substantiates the representation.<sup>117</sup>

An alternative type of order provision has the same "unless" qualification, but requires a precisely specified type of test. For example, advertisers of automobile fuel-saving attachments need "dynamometer testing of such device according to . . . test cycles established by the Environmental Protection Agency."<sup>118</sup> Similarly, tests prescribed by the Department of Energy are required for an electric space heater;<sup>119</sup> engine sequence tests from SAE Technical Report are necessary for motor oil;<sup>120</sup> tests by an accredited lab must be conducted for storm windows;<sup>121</sup> stopping, cornering, puncture, and high speed

118. John Treadwell, 106 F.T.C. 163, 170 (1985); Cliffdale Ass'n, Inc., 103 F.T.C. 110, 199 (1984); California-Texas Oil Co., 104 F.T.C. 268, 277 (1983) (two provisions); Ball-Matic Corp., Inc., 98 F.T.C. 836, 852 (1981); Great N. Am. Indus., Inc., 98 F.T.C. 817, 830 (1981); Mid-City Chevrolet, Inc., 95 F.T.C. 371, 376 (1980); C.I. Energy Dev., Inc., 94 F.T.C. 1337, 1358 (1979); RR Int'l, 94 F.T.C. 1312, 1333 (1979); Leroy Gordon Cooper, 94 F.T.C. 674, 695 (1979); American Consumer, Inc., 94 F.T.C. 648, 660 (1979); All consent except *Cliffdale*.

119. Energy Efficient Sys., Inc., 97 F.T.C. 265, 286 (1981); Boekamp, Inc., 97 F.T.C. 291, 315 (1981) (both consent).

120. Renuzit Home Prods. Co., 99 F.T.C. 291, 294 (1982) (consent).

121. Heatcool, Inc., 101 F.T.C. 24, 32 (1983) (consent).

<sup>57 (1972).</sup> All consent except Firestone, Standard Oil of California, Crown Central, and Porter and Dietsch.

<sup>113.</sup> Hugh Mooney, 85 F.T.C. at 511.

<sup>114.</sup> Crown Cent., 88 F.T.C. at 211.

<sup>115.</sup> Kettle Moraine Elec., 95 F.T.C. at 401.

<sup>116.</sup> Porter & Dietsch, 90 F.T.C. at 885.

<sup>117.</sup> General Motors, 104 F.T.C. at 512-13.

performance tests are required for automobile tires;<sup>122</sup> a competent and reliable clinical test is mandatory for an oral irrigating device;<sup>123</sup> two well-controlled clinical studies must be undertaken for acne preparations,<sup>124</sup> electric shavers,<sup>125</sup> and a topical analgesic;<sup>126</sup> and one well-controlled clinical study is compulsory for preparations relating to baldness, cellulite, anti-aging or sexual performance.<sup>127</sup>

A few provisions specify test requirements in formats other than the "unless" type.<sup>128</sup> In all provisions discussed in this article, the FTC appears to recognize no differences between "test" and alternate terms such as "study" or "investigation."

When surveys are required for the RB/S, the "unless" format is typically used. For example, Perma-Strate was told to cease claims that beauticians used, approved, recommended, or endorsed its hair straightener "unless at the time the representation is made respondents have a reasonable basis, consisting of competent and reliable survey data, to support such representation."<sup>129</sup>

A number of survey cases involved false claims of past retail prices,

124. Cooga Mooga Inc., 92 F.T.C. 310, 320 (1978); Karr Preventative Medical Prods., Inc., 94 F.T.C. 1080, 1091 (1979); Nat'l Media Group, Inc., 94 F.T.C. 1096, 1107 (1979); San-Mar Laboratories, Inc., 95 F.T.C. 236, 242-43 (1980); Harvey Glass, M.D., 95 F.T.C. 246, 252 (1980); Hayoun Cosmetique, Inc., 95 F.T.C. 794, 800 (1980) (all consent).

125. Sperry Corp., 98 F.T.C. 4, 9 (1981); DKG Advertising, 98 F.T.C. 15, 23 (1981) (agency for Sperry); North Am. Philips, 101 F.T.C. 359, 364 (1983); McCaffrey & McCall, Inc., 101 F.T.C. 367, 369 (1983) (agency for Philips) (all consent).

126. Thompson Medical Co., Inc., 104 F.T.C. 648, 844 (1984) aff'd, Thompson Medical v. F.T.C., 791 F.2d 189 (D.C. Cir. 1986). See additional provision, infra text accompanying note 182. The court agreed with Thompson that "[I]t does not appear that the FTC has ever before required clinical testing to support a nonestablishment claim." Thompson, 791 F.2d at 195. But cf., consent cases supra notes 123, 124, 125, and infra note 127. The requirement was called valid nevertheless. Thompson, 791 F.2d at 193-96.

127. U.S. v. Braswell, No. C81-558A, slip op. (N.D. Ga., Sept. 14, 1983) (final judgement and reasons for settlement) (F.T.C. consent settlement arranged by court after filing by Justice Dept. on F.T.C.'s behalf).

128. Aluminum Co. of Am., 93 F.T.C. 743, 747 (1979); Hair Extension of Beverly Hills, Inc., 95 F.T.C. 361, 367-68 (1980); Terrance D. Lesko, M.D., 96 F.T.C. 73, 79 (1980); Jordan-Simner, Inc., 95 F.T.C. 871, 879 (1980); American Home Prods. Corp., 95 F.T.C. 884, 894 (1980); Morton-Norwich Prods., Inc., 95 F.T.C. 899, 909 (1980); Benton & Bowles, Inc., 97 F.T.C. 167, 174-76 (1981) (three provisions) (agency for Shaller Rubin); Shaller Rubin Assoc., Inc., 97 F.T.C. 178, 186-88 (1981) (three provisions); Sorga, Inc., 97 F.T.C. 205, 215 (1981) (agency for American Home Products) (all consent).

129. Perma-Strate Co., 87 F.T.C. 155, 160 (1976) (consent) (Perma's agency, Merrill Kremer also a named party).

<sup>122.</sup> Bridgestone Tire Co. of Am., 86 F.T.C. 825, 830 (1975); Parker Advertising, Inc., 87 F.T.C. 68, 73 (1976) (agency for Bridgestone Tire).

<sup>123.</sup> Teledyne, Inc., 97 F.T.C. 320, 330 (1981); J. Walter Thompson Co., 97 F.T.C. 333, 336 (1981) (agency for Teledyne) (both consent)

touted as comparative prices against which the lower current prices would seem a great value. In the first of these, the advertiser was required to cease such claims "unless respondent shall have conducted, within twelve months before making any such representation. а statistically significant survev of principal retail establishments in the same trade area, which survey establishes that  $\ldots$  [such price representations are true].<sup> $n_{130}$ </sup> Later, a series of provisions addressed to similar problems required a "market survey" to establish the validity of price comparisons.<sup>131</sup>

Other cases involved false claims of demand for various kinds of workers, or for graduates of trade or technical schools, or for earnings such graduates may expect. The provisions called for "statistically valid surveys," with the following typical wording: "unless the respondents in each and every instance . . . until the passage of a base period . . . have in good faith conducted a statistically valid survey which establishes the validity of any such representation at all times when the representation is made."<sup>132</sup>

Finally, some orders offered a choice of tests or surveys. For instance, General Electric was ordered to cease representations about various household products " $[u]nless \dots$  respondent has a reasonable

132. Fuqua Indus., 85 F.T.C. 93, 111 (1975); see also World Wide Sys., Inc., 86 F.T.C. 182, 191 (1975); Lear Siegler, Inc., 86 F.T.C. 860, 868 (1975); Diesel Truck Drivers Training School, Inc., 86 F.T.C. 1062, 1069 (1975); Nationwide Training Ser., Inc., 87 F.T.C. 646, 655 (1976); Lafayette United Corp., 88 F.T.C. 683, 699-700 (1976) (all consent).

In two other cases the wording was only slightly different. M.T.I. Business Schools of Sacramento, Inc., 83 F.T.C. 1451, 1457 (1974) (two provisions); Ryder System, Inc., 90 F.T.C. 921, 931 (1977) (both consent). The most recent case required that data on job demand "shall be collected at least once every two years by a statistically valid survey of all LaSalle graduates who graduated within a period which is not less than twelve months, and which begins not more than three years before the questioning of graduates in each survey." Macmillan Inc., 96 F.T.C. 208, 328 (1980) (litigated).

<sup>130.</sup> New York Jewelry Co., 74 F.T.C. 1361, 1427 (1968), enforced, Tashof v. F.T.C., 437 F.2d 707 (D.C. Cir. 1970).

<sup>131.</sup> Dowd's, Inc., 77 F.T.C. 270, 276 (1970); Gurley Indus., 77 F.T.C. 477, 483 (1970); Voedisch Bros., Inc., 77 F.T.C. 485, 489 (1970); Standard Reference Library, Inc., 77 F.T.C. 969, 977 (1970); Zale Corp., 77 F.T.C. 1098, 1108 (1970); American Tire Co., 77 F.T.C. 1169, 1176 (1970); Carpet Specialists, 77 F.T.C. 1256, 1263 (1970); Sidlis Sales Corp., 78 F.T.C. 46, 52 (1971); Carpet Interiors, 81 F.T.C. 313, 324 (1972); Sewing Distributors, Inc., 82 F.T.C. 380, 386 (1973); Discount Carpets, Inc., 82 F.T.C. 1316, 1324 (1973); Rubins Discount Carpet Center of Va., Inc., 82 F.T.C. 1328, 1337 (1973); Freight Liquidators, 83 F.T.C. 444, 454 (1973); Classic Carpet Center, Inc., 83 F.T.C. 467, 474 (1973); Carpet Bazaar, Inc., 83 F.T.C. 1434, 1439 (1974); Atlantic Constr. & Supply Co., 83 F.T.C. 1440, 1446 (1974); Metro Passbook, Inc., 83 F.T.C. 1508, 1512 (1974); Buy-Rite Sales Corp., 84 F.T.C. 310, 318 (1974); Oden Distrib. Co., 84 F.T.C. 1125, 1132 (1974); Diener's, Inc., 84 F.T.C. 1306, 1308 (1974); Fashion Floors, Inc., 85 F.T.C. 820, 827 (1975); Mark Enterprises, Inc., 85 F.T.C. 1068, 1075 (1975); Carpets "R" Us, Inc., 87 F.T.C. 303, 340 (1976); Melvin S. Landow, 89 F.T.C. 438, 448 (1977); Grolier, Inc., 91 F.T.C. 315, (1978) (litigated), modified order, 98 F.T.C. 882 (1981), reissued order, 99 F.T.C. 379 (1982); Hiken Furniture Co., 91 F.T.C. 1115, 1128 (1978). All consent except Fashion Floors, Mark Enterprises, Carpets "R" Us, and Grolier. The Grolier provision was recently eliminated: modified order, 104 F.T.C. 639 (1984).

basis for such representation which . . . shall consist of competent and reliable studies, surveys, or scientific or engineering tests."<sup>133</sup> In that case, the respondent had made claims of dependability and low numbers of service calls on the basis of surveys, but the FTC apparently felt such claims in the future might be made on the basis of tests as well.<sup>134</sup>

What does the case record say about *when* and *why* the RB/S should require a test or survey? First, in several cases, "Cited Proof Misrepresentations" were charged or found to exist, but the order provisions were written in the RB/S format.<sup>135</sup> In two other cases, "Cited Proof Misrepresentations" were found, and provisions were written in both formats.<sup>136</sup> It is natural in such cases that the required substantiation be the same as represented in the advertising.

for a reasonable period following the introduction of a new feature or a new model of such product, respondent may make representations . . . on the basis of literature or generally recognized scientific or engineering principles, but only if respondent immediately undertakes competent and reliable studies, surveys or scientific or engineering tests relating to such representations. If the results of such studies, surveys or tests do not provide a reasonable basis for such representations with respect to the new feature or new model, respondent shall forthwith cease and desist from making such representations.

Id.

134. Other "test or survey" provisions were in Trailer Coach Assn., 84 F.T.C. '13, 718 (1974); Recreational Vehicle Inst., Inc., 84 F.T.C. 720, 727 (1974); Commercial Automotive Serv., Inc., 84 F.T.C. 637, 641 (1974); McCollum Ford Sales, Inc., 84 F.T.C. 643, 647 (1974) Camp Chevrolet, 84 F.T.C. 648, 652 (1974) (all consent). The provisions for the latter three continued:

and 2. have made available to the general public, at the point of retail sale, copies of a brief but comprehensive statement of the results and methodology of such tests or surveys, in terms understandable to the average consumer.... In immediate conjunction with the representation, respondents clearly and conspicuously disclose... where and how the test or survey results and methodology may be obtained.

Commercial Automotive, 84 F.T.C. at 642; McCollum, 84 F.T.C. at 647; Camp Chevrolet, 84 F.T.C. at 652.

Two of the five respondents mentioned tests in their advertising; none mentioned surveys. No explanation is available as to why the provisions mentioned both. The mileage and energy claims would appear to require tests.

135. Cliffdale Ass'n, Inc., 103 F.T.C. 110 (1984); Thompson Medical Co., 104 F.T.C. 648 (1984); Great N. Am. Indus., Inc., 98 F.T.C. 817 (1981); Ball-Matic Corp., 98 F.T.C. 836 (1981); Porter & Dietsch, Inc., 95 F.T.C. 806 (1980); American Consumer, Inc., 94 F.T.C. 648 (1979); Leroy Gordon Cooper, Inc., 94 F.T.C. 674 (1979); RR Int'l, Inc., 94 F.T.C. 1312 (1979); C.I. Energy Dev., Inc., 94 F.T.C. 1337 (1979); Hugh Mooney t/a Organic Masque Co., 85 F.T.C. 507 (1975); Mota-Nu, Inc., 83 F.T.C. 1467 (1974); Firestone Tire & Rubber Co., 81 F.T.C. 398 (1972); PPG Indus., Inc., 80 F.T.C. 53 (1972).

136. Standard Oil Co. of Cal., 84 F.T.C. 1401, 1490-91 (1974) (Standard's agency BBD & O also a named party); Crown Central Petroleum Corp., 84 F.T.C. 1493, 1551 (1974).

<sup>133.</sup> General Elec. Co., 89 F.T.C. 209, 218 (1977) (consent). The exception was offered that:

Other cases, however, were pure RB/S cases; in other words, tests or surveys were not advertised but were held necessary to supply the RB/S that was implied to exist. The opinion in the earliest, *Tashof*, had no comment on why the RB/S must be a survey; the need was simply taken for granted, perhaps as implicit in the nature of the claim.<sup>137</sup> In *Pfizer*, complaint counsel said tests were implied, but the Commission interpreted the issue as unfairness rather than deceptiveness. It did, however, discuss adequacy or inadequacy of evidence that fell short of the strongest type, the test. It ruled Pfizer had failed to show that lesser evidence, such as medical literature or clinical experience, would amount to a reasonable basis. Complaint counsel, on the other hand, had failed to show they could *not* amount to a reasonable basis.<sup>138</sup>

In Crown Central,<sup>139</sup> complaint counsel appealed from the initial decision's requirement of substantiation "by adequate scientific or technical data."<sup>140</sup> The Commission found:

Other factual evidence, such as research on relevant automotive engineering principles or automotive performance characteristics, may be added to evidence of tests on the advertised product to complete the substantiation picture, but the performance claims . . . could not be reasonably made without competent test data.

Furthermore, the designation of the advertised product as *Formula* CA-101 and the obviously technical nature of air pollution-related performance claims for a gasoline or gasoline additive contribute to the clear suggestion that the product has properties and characteristics which could not be fully verified other than through adequate testing.<sup>141</sup>

Much discussion in *Porter & Dietsch* was on RB/S requirements: "[R]espondents conceded that they had no tests, studies, scientific reports, or other similar information to support their implied claim that they had a reasonable basis for their weight-loss representations ...."<sup>142</sup> Emphasis, therefore, was given to the types of substantiation respondent offered. They consisted of various documentations of the characteristics of the drug, none of which were found relevant to substantiating the advertised claims.<sup>143</sup>

Id.

<sup>137.</sup> The appellate court observed that respondent had offered nothing "to support its assertion that the statistical requirement is unduly burdensome. The requirement does not appear onerous on its face." Tashof v. F.T.C., 437 F.2d 707, 715 (D.C. Cir. 1970). See discussion *supra* note 94.

<sup>138.</sup> Pfizer, Inc., 81 F.T.C. 23, 66-72 (1972) (dismissed).

<sup>139.</sup> Crown Cent., 84 F.T.C. at 1547.

<sup>140.</sup> Id. at 1531.

<sup>141.</sup> Id. at 1548-49 (emphasis in original). Another principle offered was that: When a test is cited for one performance claim or part of a performance claim, and no indication is given that equally technical representations in the same ad have no substantiation, or perhaps less adequate substantiation, the implication is clearly present that substantiation exists for all performance claims.

<sup>142.</sup> Porter & Dietsch, Inc., 90 F.T.C. 770, 868 (1977).

<sup>143.</sup> Id. at 868-72. Respondent also asked the court to find that the F.T.C. had

The generalization arising from these cases is that when advertising implies existence of an RB/S, and an RB/S could not be less than a test or survey, then the RB/S must be a test or survey. As to provisions requiring the RB/S to consist of a specific *type* of test or survey, some explanation is derivable from *Cliffdale*. A key finding in *Cliffdale* was that respondents relied unreasonably on certain "consumer type tests and reports which should not form the basis for fuel economy claims . . . ."<sup>144</sup> Apparently, the test requirement was precisely specified to preclude a similar error later in interpreting the RB/S requirement of competent and reliable tests.

The rationale for specific types of tests was further developed in the analgesics cases:<sup>145</sup> "It is well settled that well-controlled clinical trials are required to establish analgesic efficacy of a drug."<sup>146</sup> Evidence such as long-term use of a drug on the market or reports of clinical experience is not an acceptable substitute.<sup>147</sup> In response to Thompson's protest about the high quality of its expert testimony, the Commission said such testimony could be no substitute for controlled clinical testing.<sup>148</sup> The initial decision discussed and rejected various types of evidence respondent offered as substitutes for clinical tests: patents, clinical observations and opinions of physicians, user testimonials, drug compendia and general scientific literature, information on a drug's pharmacology and mechanism of action, and data on the product's marketing experience.<sup>149</sup>

The *Thompson* opinion discussed six factors it was using, cited in an appended *FTC Policy Statement Regarding Advertising Substantiation*,<sup>150</sup> to determine the degree of substantiation to require.<sup>151</sup> The first factor concerned the type of product. Because past cases involved products that posed health or safety issues and thus required a high level of substantiation, namely scientific tests, it was noteworthy that the present case also involved these issues. The second factor

146. Thompson Medical Co., Inc., 104 F.T.C. 648, 719, 822 (1984) (citations omitted).

wrongly found "scientific testing" to be the only possible reasonable basis. The court retorted that the F.T.C. had not found that, but rather had found that respondent had represented that the basis was scientific testing. Porter & Dietsch v. F.T.C., 605 F.2d 294, 302 (7th Cir. 1979).

<sup>144.</sup> Cliffdale Ass'n, Inc., 103 F.T.C. 110, 153 (1984).

<sup>145.</sup> Supra text accompanying notes 44-46.

<sup>147.</sup> Id. at 720.

<sup>148.</sup> Id. at 828.

<sup>149.</sup> Id. at 750-63.

<sup>150. 48</sup> Fed. Reg. 10471 (1983). 47 A.T.T.R. 234 (1984), appended to Thompson Medical Co., Inc., 104 F.T.C. 648, 839 (1984).

<sup>151.</sup> Thompson, 104 F.T.C. at 821-26.

concerned the type of claim. A claim whose truth or falsity would be difficult for consumers to evaluate, as in this instance, would call for the high level of substantiation that scientific tests represent. The FDA's panels on analgesics, the initial decision said, noted that pain is subjective and efficacy cannot be shown simply by producing positive studies that do not meet the standards of science.<sup>152</sup> The third and fourth factors were the benefit of a truthful claim which, in this case, would be substantial for both consumers and the respondent, and the ease, meaning cost, of developing substantiation, which would be low relative to the potential volume of the market. The ratio of benefit to cost thus being high, the conclusion was that a high level of substantiation would not deter product development. The fifth factor involved the consequences of a false claim. Although the Commission agreed with the ALJ that the economic consequences were substantial, it disagreed that the health consequences would be. The sixth factor was the level of substantiation experts find reasonable, which was determined to be scientific tests.

The opinion also said the test requirement paralleled the FDA standard.<sup>153</sup> Thompson Medical had argued that in the case of a mild and harmless topical analgesic, the requirement of scientific tests should be relaxed or dispensed with. This position, however, was contrary to the prevailing and accepted view of the medical and scientific community and thus was rejected by the FDA.<sup>154</sup> Further, the FDA had refused to find the drug effective.<sup>155</sup> If the FTC were to hold that, for advertising purposes, efficacy claims were supported by adequate medical/scientific substantiation, based on essentially the same evidence considered by the FDA, this would be tantamount to establishing a lower standard of efficacy for OTC drug advertising than that applicable to OTC drug marketing.<sup>156</sup>

In summary, the required RB/S will include a test or survey when: (1) the advertisement refers to such test or survey, or (2) the required RB/S cannot consist of any lesser standard. If the RB/S must be a certain *type* of test or survey, then that type will be precisely specified. Where these two situations do not apply, the specified RB/ S may consist of a lesser standard of evidence (see Sections VII-VIII).

# VII. RB/S MUST CONSIST OF A TEST OR SURVEY OR ELSE AN ALTERNATIVE TYPE OF EVIDENCE

These order provisions specify a test or survey as one type of evi-

<sup>152.</sup> Id. at 720. 153. Id. at 826. 154. Id. at 720. 155. Id. at 769-70. 156. Id. at 772.

dence that can constitute the RB/S. They also specify alternative types. A large number of provisions specify the alternatives to tests only vaguely.<sup>157</sup> The following sampling illustrates the many variations in wording. Some variations may differ significantly in meaning while some may not; the cases provide no discussion on the point:

*Provided, however*, that the use of such terms shall not be: prohibited if . . . statements concerning such terms are substantiated by competent scientific tests or other objective material which provide a reasonable basis for the representations made, and the substantiation materials are either (i) available for public inspection, or (ii) otherwise available to the Federal Trade Commission to determine compliance with this order.<sup>158</sup>

[u]nless such statements or representations are true and unless, at the time the statements or representations are made, Sears, Roebuck and Co. possesses and relies on a reasonable basis for such statements or representations, which shall consist of competent and reliable tests, or other competent and reliable evidence which substantiates such statements or representations.  $^{159}$ 

[u]nless respondent possesses a reasonable basis for making that claim. A rea-

157. Saga International, No. C-3196, F.T.C. slip op. (1986) (two provisions); National Energy Associates, No. C-3179, F.T.C. slip op., at 10 (1986); Blue Lustre, No. C-3195, F.T.C. slip op., at 3 (1986); Sunbeam, No. C-3181, F.T.C. slip op., at 3 (1986) (two provisions); North Am. Philips, No. C-3180, F.T.C. slip op., at 5 (1985) (two provisions); Barry Bricklin, 106 F.T.C. 115, 161 (1985); Chesebrough-Ponds, 106 F.T.C. 567, 573 (1985); Weider, 106 F.T.C. 584, 598 (1985); Larry Brog, 106 F.T.C. 576, 582 (1985); Wein Products, 106 F.T.C. 51, 62 (1985); (two provisions); Associated Mills, 106 F.T.C. 5, 23 (1985); Young & Rubicam/Zemp, 105 F.T.C. 317, 339 (1985) (agency for Rush-Hampton); Rush-Hampton, No. 9167, F.T.C. slip op., at 5 (1985); P. Leiner Nutritional Products, 105 F.T.C. 291, 304 (1985); Sentronic, 105 F.T.C. 197, 225-26 (1985) (two provisions); Thomas A. Dardas, 104 F.T.C. 562, 573 (1984); Cynex Manuf. Corp., 104 F.T.C. 464, 475 (1984); Adria Laboratories, Inc., 103 F.T.C. 512, 526 (1984); Pharmtech Research, Inc., 103 F.T.C. 448, 459 (1984); Spinal Health Services Inc., 102 F.T.C. 1319. 1323 (1983); Foote, Cone & Belding Adv., Inc., 102 F.T.C. 1274, 1283 (1983) (agency for Amana); Amana Refrigeration, Inc., 102 F.T.C. 1262, 1266 (1983); Sterling Drug, Inc., 102 F.T.C. 395, 804 (1983); Bristol-Myers Co., 102 F.T.C. 21, 392 (1983); Stihl Inc., 101 F.T.C. 840, 851 (1983) (Stihl's agency, Stuart Food also a named party); Meredith Corp., 101 F.T.C. 390, 405 (1983); Plaskolite Inc., 101 F.T.C. 344, 349 (1983); Champion Home Builders Co., 101 F.T.C. 316, 324 (1983) (two provisions); Teledyne, Inc., 97 F.T.C. 320, 330 (1981); Sears, Roebuck & Co., 95 F.T.C. 406, 525-26 (1980); Clorox Co., 94 F.T.C. 1, 4 (1979); Block Drug Co., Inc., 92 F.T.C. 852, 853 (1978) (two provisions addressed to Block's agency, Grey Advertising, also a named party); Astor-Scott Inc., 89 F.T.C. 536, 542-43 (1977) (two provisions); Robertson Prods., 87 F.T.C. 255, 264 (1976); Soft Sheen Co. Inc., 87 F.T.C. 164, 170 (1976) (two provisions); Perma-Strate Co., 87 F.T.C. 155, 161 (1976) (Perma's agency, Merrill Kremer, also a named party); STP Corp., 87 F.T.C. 56, 66 (1976); (STP's agency, Stern, Walters & Simmons also a named party); Hercules Inc., 84 F.T.C. 605 (1974), modified, 86 F.T.C. 1236, 1238 (1975); Yamaha Int'l Corp., 86 F.T.C. 973, 979-80 (1975) (two provisions); Union Carbide Corp., 84 F.T.C. 591, 597-602 (1974) (four provisions); K Mart Enters., Inc., 84 F.T.C. 574, 577 (1974); Pay Less Drug Stores Northwest, Inc., 82 F.T.C. 1473, 1479 (1973); E.J. DuPont DeNemours & Co., 81 F.T.C. 169, 173 (1972); Proctor & Gamble Co., 80 F.T.C. 181, 186 (1972) (two provisions). All consent except Sears, Roebuck, Bristol-Myers, and Sterling Drug. See also modification in American Home Products, discussed supra note 56.

158. Hercules, Inc., 86 F.T.C. at 1238.

159. Sears, Roebuck and Co., 95 F.T.C. at 525-26.

sonable basis for such a claim shall consist of competent and reliable scientific evidence supporting that claim. Well-controlled clinical tests conducted in accordance with the criteria set forth . . . shall be deemed to constitute a reasonable basis for a claim.<sup>160</sup>

unless at the time of making such representation respondent possesses and relies upon a reasonable basis for such representation. A reasonable basis shall consist of competent and reliable evidence which substantiates such representation. To the extent the evidence of a reasonable basis consists of scientific or professional tests, experiments, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, such evidence shall be 'competent and reliable' only if those tests [etc.] are conducted in an objective manner by persons qualified to do so, using procedures generally accepted in the profession or science to yield accurate and reliable results.<sup>161</sup>

Other provisions are more specific, such as describing the alternatives to tests as consisting of expert opinion.<sup>162</sup> Elsewhere the alternatives were standards promulgated by designated organizations, such as the Air Conditioning and Refrigeration Institute,<sup>163</sup> or, for over-the-counter drugs, the Food & Drug Administration.<sup>164</sup>

Where surveys were required, the alternatives were vague. Claims about the earning successes of a school's graduates were prohibited unless "such substantiation include[d] a statistically valid survey or other appropriate substantiating material which establishes the reasonable basis for each such statement or representation."<sup>165</sup>

Litton was ordered to cease claims about microwave ovens: "unless and only to the extent that respondents possess and rely upon a reasonable basis for such representation at the time of its initial and each subsequent dissemination. Such reasonable basis shall consist of competent and reliable surveys and/or other competent and reliable

163. City Investing Co., 83 F.T.C. 1078, 1082-83 (1973) (consent) (two provisions); Whirlpool Corp. & Doyle Dane Bernbach, Inc., 83 F.T.C. 1830, 1835, 1837 (1974) (consent).

165. Career Academy Inc., 84 F.T.C. 453, 465 (1974) (consent).

National Systems was similar. National Systems Corp., 93 F.T.C. 58, 68-69 (1979) (two provisions) (consent). All other provisions involving such claims required surveys with no alternative, see supra note 132.

<sup>160.</sup> Bristol-Myers Co., 102 F.T.C. at 392.

<sup>161.</sup> Sunbeam, No. C-3180, slip. op. at 5 (1986).

<sup>162.</sup> Ford Motor Co., 84 F.T.C. 729, 735 (1974) (consent), aff'd, Ford and Thompson v. F.T.C., 547 F.2d 954, 961 (6th Cir. 1976), cert. denied, 431 U.S. 915 (1977); J. Walter Thompson Co., 84 F.T.C. 736, 742 (1974) (consent), aff'd, Thompson v. F.T.C., 547 F.2d 954 (6th Cir. 1976), cert. denied, 431 U.S. 915 (1977) (agency for Ford); Ford Motor Co., 87 F.T.C. 756 (1976) (partial order and remand), 93 F.T.C. 873, 881 (1979) (consent); Thompson, 94 F.T.C. 331, 338 (1979) (consent) (agency for Sears); Montgomery Ward & Co., Inc., 95 F.T.C. 265, 274 (1980); U.S. v. Braswell, No. C81-558A, slip. op. (N.D. Ga., Sept. 14, 1983).

<sup>164.</sup> Biopractic Group Inc., 104 F.T.C. 845, 850 (1984) (consent); AHC Pharmacal, Inc., 95 F.T.C. 528 (1980) (consent), modified, 101 F.T.C. 40, 45 (1983); Thompson Medical Co., Inc., 104 F.T.C. 648, 844 (1984); Ogilvy & Mather Int'l Inc., 101 F.T.C. 1, 15 (1983) (consent) (agency for Thompson Medical); see also Chesebrough-Ponds, 106 F.T.C. 567, 573 (1984). The Thompson Medical provision followed that already discussed, supra text accompanying note 126; respondent had been charged with a "Cited Proof Misrepresentation"; see supra note 47.

evidence which substantiates the representation."166

What rationale exists for RB/S requirements specifying tests or surveys only in conjunction with alternatives? Among the few litigated cases<sup>167</sup> was *Sears*. After complaint counsel asked for a requirement of "valid and scientific tests," Sears cited *Pfizer* for the proposition that scientific tests would not invariably be required.<sup>168</sup> The initial decision responded that "[t]he product was a dishwasher, not a food, drug, or potentially hazardous product,"<sup>169</sup> thus neither safety nor health were involved:

the consequences of Sears' falsity did not involve possible personal injury or property damage. Sears, therefore, was entitled to rely upon other evidence and information not necessarily rising to the level of 'adequate and well-controlled scientific studies or tests,' so long as that evidence and information did, in fact, provide a reasonable basis for the claim.<sup>170</sup>

The ALJ's argument was adopted by the Commission. Shortly thereafter, *Litton* was granted a similar alternative on the basis that "[a] formulation nearly identical to that recommended by complaint counsel was recently applied by the Commission in *Sears, Roebuck & Co.*..."<sup>171</sup> What was applicable to dishwashers and tests became applicable to microwave ovens and surveys.

The original AHC Pharmacal provision did not allow the alternative of an FDA standard.<sup>172</sup> Later, the FTC reopened the proceeding on petition from AHC based on an FDA panel conclusion that the drug was generally recognized as safe and effective. Commissioner Pertschuk stated that the modification<sup>173</sup> would enable advertisers to take FDA findings out of context to make claims they would not support.<sup>174</sup> Commissioner Clanton disagreed because claims would still be prohibited unless supported by " 'competent and reliable scientific or medical evidence.' "<sup>175</sup>

168. Sears, Roebuck & Co., 95 F.T.C. 406, 481 (1980).

175. Id. at 46. See also American Home Prods. Corp., 77 F.T.C. 726 (1970), modified, No. 8641 F.T.C. slip op. (1986).

<sup>166.</sup> Litton Indus., Inc., 97 F.T.C. 1 (1981), modified, Litton v. F.T.C., 676 F.2d 364 (9th Cir. 1982), modified order, 100 F.T.C. 457, 458 (1982).

<sup>167.</sup> No answer was given in *Ford Motor*, in which the initial decision had said the reasonable basis could only be tests. Ford Motor Co., 87 F.T.C. 756, 791 (1974). After the remand, a second hearing never occurred because of the consent settlement that permitted an alternative to testing. *See supra* note 162.

<sup>169.</sup> Id. at 482.

<sup>170.</sup> Id.

<sup>171.</sup> Litton, 97 F.T.C. at 74.

<sup>172.</sup> A.H.C. Pharmacal Inc., 95 F.T.C. 528, 534 (1980).

<sup>173.</sup> A.H.C. Pharmacal, 101 F.T.C. 40, 45 (1983).

<sup>174.</sup> Id. at 48.

Bristol-Myers dealt with both a "Cited Proof Misrepresentation"<sup>176</sup> and an RB/S Misrepresentation. Two clinical tests were absolutely required for the Cited Proof Misrepresentation and the same was held sufficient, but perhaps not necessary, for the RB/S requirement:<sup>177</sup> "Whether any lesser amount of evidence could also constitute a reasonable basis is more difficult to determine. . . . [W]e cannot rule out the possibility that other types of evidence might be adequate . . . ."<sup>178</sup> Thus, in dubious situations, Bristol could either conduct the two clinical tests, request an advisory opinion, or qualify its advertising to inform consumers of the lesser substantiation.<sup>179</sup>

Bristol argued on appeal that the result was unduly vague, citing the American Home Products appeal which stated that "any order which essentially relies upon 'reasonable basis' language will be imprecise . . . ."<sup>180</sup> However, the court affirmed, stating that "absolute precision is not possible in certain FTC orders, and we have upheld reasonable basis provisions formulated in substantially identical terms."<sup>181</sup>

Thompson Medical involved a provision absolutely requiring tests in addition to the provision seen here.<sup>182</sup> The former applied to comparative efficacy or safety claims; the latter applied to noncomparative efficacy or safety claims. For the latter, the FDA standard was offered as an alternative, whether or not it called for the clinical

Id. at 376 n. 100. The Commission further held that:

Accordingly, order Paragraph II does permit respondent to substantiate its claims with evidence other than two clinical tests if it can show that such evidence is sufficiently reliable to support a good faith belief in the truth of the claim. Such a showing must be based on the factors set forth in the *Pfizer* line of cases... Concededly permitting such a showing creates some ambiguity regarding the absolute minimum amount of evidence necessary to provide a reasonable basis... But this is inherent in any reasonable basis order by virtue of the factors set forth in *Pfizer*.

Id. at 376-77.

179. Id. at 377.

180. Bristol-Myers Co. v. F.T.C., 738 F.2d 554, 560 (2d Cir. 1984) (citing American Home Products v. F.T.C., 695 F.2d 681, 710) (3d Cir. 1982)).

181. Bristol-Myers, 738 F.2d at 560. The Bristol-Myers court cited the Jay Norris and Fedders cases as precedents. Both these cases cited infra note 187.

The same order provision was explained the same way in *Sterling*, where the resulting "flexibility" was called an appropriate balance between the need for clear standards and the need to prevent repeated violations. Sterling Drug, 102 F.T.C. at 796. The point was affirmed by the court on appeal, Sterling Drug Inc., v. F.T.C., 741 F.2d 1146, 1156-57 (9th Cir. 1984).

182. For absolute requirement, see supra note 126 and accompanying text; for alternative requirement, see note 164.

<sup>176.</sup> Supra note 42 and accompanying text.

<sup>177.</sup> Bristol-Myers Co., 102 F.T.C. 21, 376 (1983).

<sup>178.</sup> Id. The opinion further states:

For example, in some situations the FDA will permit a drug to be marketed without clinical testing if nonclinical tests show the drug to be as effective as another drug whose effectiveness has already been established by clinical tests.

tests.<sup>183</sup> However, the opinion observed that there was "no reason to think [the] FDA would dispense with the requirement of the two well-controlled clinicals."<sup>184</sup> Thus, for practical purposes, the provision offering an alternative was little different from the one absolutely requiring tests.

In summary, tests or surveys are not necessarily required when an RB/S is required. Alternatives are sometimes allowed when less sensitive issues are involved, or when the alternatives are virtually equivalent to tests or surveys. Although the alternatives ostensibly create a lower standard of evidence, such standards seem only slightly lower, and in many cases are essentially the same. The Pertschuk dissent,<sup>185</sup> however, argues that such provisions could serve as loopholes to permit lower standards. These provisions are, on the average, more recent than those in the previous section.<sup>186</sup>

#### VIII. RB/S CONSISTS OF TEST-LIKE OR SURVEY-LIKE EVIDENCE

These order provisions call for the RB/S to consist of evidence that could include tests or surveys but which at the least seems test-like or survey-like. Descriptive terms such as "scientific," "objective," or "competent" make the requirements seem little different from tests or surveys. The RB/S provisions omitted from this article lack such language that inferentially associates them with tests or surveys.

A large number of provisions fall in this category.<sup>187</sup> Given the

<sup>183.</sup> Thompson Medical Co., Inc., 104 F.T.C. 648, 826 n.73 (1984).

<sup>184.</sup> Id.

<sup>185.</sup> A.H.C. Pharmacal, Inc., 101 F.T.C. 40, 48 (1983).

<sup>186.</sup> Compare cases supra note 157 to those supra note 112.

<sup>187.</sup> Pittsburgh Penn Oil, No. D-9203, F.T.C. slip op. (1986); Figgie, No. 9166, F.T.C. slip op. (1986); Descent Control, 105 F.T.C. 280, 285 (1985); Charles E. Weller, 104 F.T.C. 1089, 1093 (1984); Cliffdale Assoc., Inc., 103 F.T.C. 110, 200 (1984); Sovereign Chem. & Petroleum Prods., Inc., 104 F.T.C. 478, 482 (1984); Estee Corp., 102 F.T.C. 1804, 1811 (1983) (two provisions); Sterling Drug, Inc., 101 F.T.C. 375, 379-80 (1983) (three provisions) (Sterling's agency, SSC&B also a named party); McCaffrey and Mc-Call, Inc., 101 F.T.C. 367, 369 (1983) (agency for North American Philips); North Am. Philips Corp., 101 F.T.C. 359, 365 (1983); Ball-Matic, Inc., 98 F.T.C. 836, 853 (1981); Great N. Am. Indus., 98 F.T.C. 817, 831 (1981); Standard Brands, Inc., 97 F.T.C. 233, 243 (1981); Ted Bates & Co., Inc., 97 F.T.C. 220, 230 (1981) (agency for Standard Brands); Sorga, Inc., 97 F.T.C. 205, 215 (1981); Shaller Rubin Assoc., Inc., 97 F.T.C. 178, 186 (1981); Benton & Bowles, Inc., 97 F.T.C. 167, 174 (1981) (agency for Shaller Rubin); Dancer-Fitzgerald-Sample, Inc., 96 F.T.C. 1, 15 (1980) (agency for Sterling Drug); Morton-Norwich Prods., Inc., 95 F.T.C. 899, 908 (1980); American Home Prods. Corp., 95 F.T.C. 884, 894 (1980); Jordan-Simner, Inc., 95 F.T.C. 871, 879 (1980); Gordon Cooper, 94 F.T.C. 674, 697 (1979); Admarketing, Inc., 94 F.T.C. 664, 672 (1979) (agency for Gordon Cooper); American Consumer, Inc., 94 F.T.C. 648, 661 (1979); Jay Norris Corp., 91 F.T.C. 751 (1978), aff'd and modified, 598 F.2d 1244 (2d Cir. 1979), cert. denied, 444

types of products, the required evidence generally seems more testlike than survey-like. The following sampling illustrates the many variations in wording. Any significance of the differences is not discussed in the cases:

unless at the time of such representation respondent has a reasonable basis for such statement or representation, which shall consist of competent scientific, engineering or other similar objective material or industry-wide standards based on such material;  $^{188}$ 

unless petitioners have a reasonable basis for the representation(s) consisting of competent and objective material, available in written form, that fully and completely substantiates such characteristic(s); $^{189}$ 

unless, at the time of making the representation, respondents possess and reasonably rely upon competent and reliable evidence that substantiates such representation;  $^{190}$ 

unless, at the time the representation is made, Descent Control possesses and relies upon a reasonable basis for the representation consisting of competent and reliable objective evidence substantiating the representation.<sup>191</sup>

Why is the RB/S defined in these ways? In *Jay Norris*, the initial decision noted that complaint counsel's proposed order called for "competent scientific tests' or 'competent objective material.'"<sup>192</sup> Noting respondent was a mail-order business, the ALJ limited the requirement to "competent objective material."<sup>193</sup> As to whether the terms "competent," "full," and "complete" as applied to substantiation, were unduly vague, the Commission said preceding cases "provide ample guidance" and that "the general meaning of the terms is readily understood."<sup>194</sup>

A mail-order business may merit leniency because it is a step re-

- 190. Cliffdale, 103 F.T.C. at 200.
- 191. Descent Control, 105 F.T.C. 280, 285 (1985).
- 192. Jay Norris, 91 F.T.C. at 823.

193. Id. This was changed by the Commission to "competent and objective material." Id. at 865 (not changed on appeal).

194. Id. at 857 (aff'd on appeal, 598 F.2d at 1250).

U.S. 980 (1979), modified order, 94 F.T.C. 415 (1979) (modified provision published, 598 F.2d at 1253, but not published in modified order; see explanation, 94 F.T.C. at 415) (first provision); 94 F.T.C. at 423 (second provision); Vital-E, 92 F.T.C. 880, 897 (1978); Owens-Corning Fiberglas Corp., 88 F.T.C. 465 (1976), modified, 97 F.T.C. 135, 136 (1981); Sonotone Corp., 88 F.T.C. 368, 373-74 (1976) (three provisions); Beltone Elecs. Corp., 88 F.T.C. 336, 342-44 (1976) (three provisions); Dahlberg Elecs., Inc., 88 F.T.C. 319, 331, 333 (1976) (two provisions); Radioear Corp., 88 F.T.C. 308, 314-16 (1976) (three provisions); Qualitone, Inc., 88 F.T.C. 287, 293-95 (1976) (three provisions); Nagle, Spillman & Bergman, Inc., 88 F.T.C. 244, 252-53 (1976) (four provisions) (agency for Adolph's); Le Conte Cosmetics, Inc., 87 F.T.C. 1348, 1356 (1976); Allied Stores, 86 F.T.C. 1074, 1078 (1975); Fedders Corp., 85 F.T.C. 38, 69 (1975), aff'd sub nom., Fedders Corp. v. F.T.C., 529 F.2d 1398 (2d Cir. 1976), cert. denied, 429 U.S. 818 (1976); General Foods Corp., 84 F.T.C. 1572, 1575 (1974); Wasem's, Inc., 84 F.T.C. 209, 213 (1974); Whirlpool and DDB, 83 F.T.C. 1830, 1834, 1837 (1974) (two provisions for each respondent); Biochemic Research Found. Corp. & Doyle Dane Bernbach, Inc., 83 F.T.C. 1096, 1102 (1973); City Investing Co., 83 F.T.C. 1078, 1083 (1973); Volvo, Inc., 82 F.T.C. 1851, 1857 (1973); Thomas J. Lipton, 82 F.T.C. 1493, 1500 (1973) (two provisions). All consent except Fedders, Jay Norris, and Cliffdale.

<sup>188.</sup> Fedders Corp., 85 F.T.C. at 69.

<sup>189.</sup> Jay Norris, 598 F.2d at 1253 (first provision).

moved from manufacturing. But none of the cases involving manufacturing explains why its RB/S has no specific reference to tests or surveys. All of the product claims could easily be subjected to testing; hearing aids are a good example.<sup>195</sup> Of course, provisions that define the RB/S in this most favorable way are in keeping with the observations of *Pfizer* that the nature of a reasonable basis will vary from case to case, and may include such things as expert opinion, existing literature, and the state of knowledge generally in a field.<sup>196</sup>

Another explanation is that several such provisions appear to play a secondary role to other provisions that absolutely require tests.<sup>197</sup> In *Cliffdale* the provisions applying to the products featured in the advertising<sup>198</sup> called for tests absolutely, while the provision calling only for "competent and reliable evidence" covered the advertising of any other product.<sup>199</sup> The latter thus may be interpreted as a "throw-in" supplementary to, and consequently less significant than, the principal provision.

In summary, the required evidence for an RB/S may sometimes be merely test-like or survey-like. This may seem to involve "lesser" criteria, but certainly such cited terms as "competent and reliable" and "scientific" imply a testing standard quite often. These provisions do not omit testing or surveying entirely, but they allow the advertiser maximum flexibility in finding alternatives. Technically, they do not allow testing to be avoided where it is the only way to achieve the RB/S. Still, there seems little question that advertisers would find these provisions less burdensome than those mentioning tests or surveys explicitly.

#### IX. Specifications for Tests and Surveys.

The previous sections have made occasional reference to the characteristics required in tests and surveys. The full references are presented in this section, covering the ways in which such require-

<sup>195.</sup> See, e.g., Sonotone Corp., 88 F.T.C. 368 (1976); Beltone Elecs. Corp., 88 F.T.C. 336 (1976); Dahlberg Elecs., Inc., 88 F.T.C. 319 (1976); Radioear Corp., 88 F.T.C. 308 (1976); and Qualitone, Inc., 88 F.T.C. 287 (1976).

<sup>196.</sup> See, e.g., supra text accompanying note 100.

<sup>197.</sup> See, e.g., Cliffdale Assoc., Inc. 103 F.T.C. 110, 200 (1984); McCaffrey and McCall, Inc. 101 F.T.C. 367, 369 (1983); North Am. Philips Corp., 101 F.T.C. 359, 365 (1983); Ball-Matic Corp, Inc., 98 F.T.C. 836, 853 (1981); Great N. Am. Indus., Inc., 98 F.T.C. 817, 831 (1981); Standard Brands, Inc., 97 F.T.C. 233, 243 (1981); Ted Bates & Co., Inc., 97 F.T.C. 220, 230 (1981).

<sup>198.</sup> See supra note 118 and accompanying text.

<sup>199.</sup> Cliffdale Assoc., Inc., 103 F.T.C. 110, 200 (1984).

ments are specified, defined, qualified, explained, or otherwise discussed. Included also are the reasons given for such specifications, and the decisions establishing whether various tests or surveys satisfy them.

What is acceptable must be inferred from what is forbidden. Nowhere has the FTC offered a comprehensive statement of what is acceptable. However, the FTC has expressed its interest in promoting acceptability by its statement in *Litton* that it worded the order to avoid "discouraging in any way the proper use of survey-based advertising."<sup>200</sup>

### A. Tests

The tests discussed are of two types, depending on the products involved. The first involves clinical tests of drugs and medical devices, which emphasize subjective responses of consumers. All tests examine product characteristics and performance, but assessment of a drug lies not so much in its ingredients per se as in the consumer's reaction to it. The second type, scientific tests of a more general sort, involves observing the product per se apart from consumer response.

1. Clinical Tests of Devices and Drugs, Mostly Analgesics

In *Pfizer*, complaint counsel called for "prior, fully documented, adequate and well-controlled scientific studies or tests"<sup>201</sup> of claims that Un-Burn would relieve pain in sunburned skin. Although counsel showed that the Food & Drug Administration had issued criteria for such tests,<sup>202</sup> counsel ultimately rested its case on the "ordinary dictionary definitions" of the words in its proposed requirement.<sup>203</sup> For that reason, the exacting details found in later decisions were not articulated.

*Pfizer*, however, noted a number of principles which have since been followed.<sup>204</sup> A test used as support should be an adequate and well-controlled scientific test. It should be germane to the claim; thus, testing for safety and antiseptic effects did not amount to support for claims of efficacy and anesthetic effects. Nor could guinea pig tests substantiate effects on humans. A pre-existing test protocol is usually essential, and double-blinded scientific tests are strongly desirable. Tests conducted after making the claims are insufficient to meet the reasonable basis requirement. And finally, a valid efficacy

<sup>200.</sup> Litton Indus., Inc., 97 F.T.C. 1, 75 (1981).

<sup>201.</sup> Pfizer, Inc., 81 F.T.C. 23, 25 (1972).

<sup>202.</sup> Id. at 65-66.

<sup>203.</sup> Id.

<sup>204.</sup> Id. at 66-68.

test for a competing product of similar composition might have provided a reasonable basis for a similar efficacy claim for Un-Burn. The way in which these principles were developed in subsequent cases is discussed under a variety of topics, as follows.

## a. Definitions of Clinical Tests

The post-*Pfizer* sophistication reached its greatest development in the litigated analgesics cases. The first, *American Home Products*, called for:

[t]wo or more adequate and well-controlled clinical investigations, conducted by independent experts qualified by training and experience to evaluate the comparative effectiveness or comparative freedom from side effects of the drugs involved.... The investigations shall be conducted in accordance with the procedure set forth below:

At least one of the adequate and well-controlled clinical investigations to evaluate the comparative effectiveness of the drug shall be conducted on any disease or condition referred to, directly or by implication; or, if no specific disease or condition is referred to, then the adequate and well-controlled clinical investigations shall be conducted on at least two conditions or diseases for which the drug is effective. The clinical investigations shall be conducted as follows:

1. The subjects must be selected by a method that: a. Provides adequate assurance that they are suitable for the purposes of the investigation, and diagnostic criteria of the condition to be treated (if any); b. Assigns the subjects to the test groups in such a way as to minimize bias; and c. Assures comparability in test and control groups of pertinent variables, such as age, sex, severity or duration of disease or condition (if any), and use of drugs other than the test drugs.

2. The investigations must be conducted double-blind, and methods of double-blinding must be documented. In addition, the investigations shall contain a placebo control to permit comparison of the results of use of the test drugs with an inactive preparation designed to resemble the test drugs as far as possible.

3. The plan or protocol for the investigations and the report of the results shall include the following: a. A clear statement of the objective of the investigation; b. An explanation of the methods of observation and recording of results, including the variables measured, quantitation, assessment of any subject's response and steps taken to minimize bias on the part of subject and observer; c. A comparison of the results of treatments or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data; d. A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.<sup>205</sup>

Definitions also occurred in other analgesics cases<sup>206</sup> and in cases

<sup>205.</sup> American Home Prods. Corp. v. F.T.C., 101 F.T.C. 698, 699-700 (1983).

<sup>206.</sup> The definition in *Bristol-Myers* is the same as for *American Home Products*, with the following added:

A test or investigation which is not conducted in accordance with these proce-

involving other products.<sup>207</sup>

#### b. Number of Tests Required

Two clinical tests were required for comparative establishment efficacy claims, as in *American Home Products*:

The ALJ stated that while there may be "a number of respected clinical pharmacologists who will be satisfied by a single well-controlled clinical demonstration," he felt this fact alone was insufficient

dures may be used to establish a claim only if respondent can show that, notwithstanding the failure to satisfy these procedures, the test or investigation would still be generally accepted by the relevant scientific community as sufficient to establish the truth of the claim.

Bristol-Myers Co., 102 F.T.C. 21, 391 (1983). This addition was added later to American Home Prods., 103 F.T.C. at 530.

The definition in *Sterling Drug* is the same as in *Bristol-Myers*, absent the phrases "comparative freedom from side effects" and "freedom from side effects." Sterling Drug, Inc., 102 F.T.C. 395, 803 (1983).

The definition used in *Thompson Medical* provides for "at least two adequate and well-controlled, double-blinded clinical studies which conform to acceptable designs and protocols and are conducted by different persons, independently of each other. Such persons shall be qualified by training and experience to conduct such studies." Thompson Medical Co., 104 F.T.C. 648, 844 (1984). The definition for its agency is similar. See Ogilvy & Mather Int'l, Inc., 101 F.T.C. 1, 15 (1983).

207. In *Teledyne*, involving the Water Pik oral irrigating device, a clinical test was defined as

[o]ne in which a person with skill and expertise in the field conducts a wellcontrolled test on human subjects, using those testing procedures generally accepted in the profession which ensure accurate and reliable results, and evaluates its results in a disinterested manner. The results of the tests must be clinically significant, which requires that the test be, among other things, of sufficient duration to ensure that the results are not materially distorted by any unusual short term practices or temporary physical conditions of the test subjects (as such practices or conditions related to the test conditions).

Teledyne, Inc., 97 F.T.C. 320, 330-31 (1981). The order for Teledyne's agency was almost the same: Thompson, 97 F.T.C. 333, 336 (1981).

For shavers claimed to be efficacious for "razor bumps" experienced by black men: "at least two well-controlled clinical studies which conform to acceptable designs and protocols and are conducted by different persons independently of each other. Such persons shall be qualified by training and experience to treat "razor bumps" and to conduct the aforementioned studies." Sperry Corp., 98 F.T.C. 4, 9 (1981); DKG Advertising, Inc., 98 F.T.C. 15, 23 (1981) (agency for Sperry); North Am. Philips Corp., 101 F.T.C. 359, 364 (1983); McCaffrey & McCall, Inc., 101 F.T.C. 367, 369 (1983) (agency for Philips) (all consent).

For hair restorative products: "one well-controlled, double-blinded clinical study that conforms to acceptable designs and protocols." U.S. v. Braswell, No. C81-588A, slip op. at 3 (N.D. Ga. Sept. 14, 1983). See supra note 127.

208. American Home Prods., 98 F.T.C. at 377-78. See discussion of establishment claims, supra text Section III.A.2.

to "argue that the rigors of established research methodology in clinical pharmacology should be discarded in advertising regulation," especially where the question was of superior effectiveness rather than mere effectiveness.<sup>209</sup>

These conclusions were described as fully consistent with and reflected in the regulations of the Food and Drug Administration: "[T]he FDA is now directed to refuse approval of an NDA [new drug application] in the absence of 'substantial evidence' that the drug is effective for its indicated uses . . . 'Substantial evidence' is defined in the Act to mean: evidence consisting of adequate and well-controlled [clinical] investigations."<sup>210</sup>

The two-test requirement was extended to nonestablishment claims in *Thompson Medical*.<sup>211</sup> On appeal, the court agreed the re-

Bristol-Myers, 102 F.T.C. at 337. On appeal Bristol argued the correct requirements should be "clinical or other experience, tests, or other scientific data," but the court decided the F.T.C. properly determined that only two well-controlled clinical studies could establish superior freedom from side effects. Bristol-Myers v. F.T.C., 738 F.2d 554, 559 (2d Cir. 1984). The American Home Products appeal was cited as precedent. Id. Sterling agreed with Bristol. See Sterling, 102 F.T.C. at 763. Sterling argued on appeal that "a therapeutic judgment comparing brands of the same drug could be based on pharmacological and other nonclinical data," but the court, though acknowledging an evidentiary conflict, said it could not reweigh the evidence. Id., 741 F.2d at 1153.

210. American Home Prods., 98 F.T.C. at 378-79. Similar comments appeared in Bristol-Myers, 102 F.T.C. at 337, and Sterling Drug, 102 F.T.C. at 768-69. Thompson Medical observed that FDA panels on analgesics required a minimum of two positive well-controlled trials by different investigators or laboratories to demonstrate effectiveness. Thompson Medical, 104 F.T.C. at 720. Replication was necessary because of the potential for systematic bias and random error in any clinical trial. Even an experienced investigator may use an aberrant methodology, or some unexpected flaw or anomaly in the randomized population may bias the results. Respondent argued that the medical community does not typically require two tests, but the Commission rejected the idea. Id. at 827. Respondent argued that the FDA does not always require two tests, but this was rejected as not disturbing the general rule. Id. Being consistent with FDA requirements, however, does not automatically make FDA determination a suitable alternative. That could not be so for Bristol, the appellate court said, because FDA dealt with absolute and not comparative levels of efficacy and safety. However, should the FDA do the appropriate studies, Bristol could rely on them. Bristol-Myers, 738 F.2d at 558-60.

211. Thompson Medical, 104 F.T.C. at 844. The requirement was absolute for comparative claims, *id.*, while for noncomparative claims an alternative requirement was

<sup>209.</sup> Id. at 306 n.42. Similarly, Bristol-Myers stated that:

<sup>[</sup>I]n order to establish the comparative efficacy of an analgesic, two well-controlled studies meeting all the criteria set forth . . . are required. . . . Replication reduces the possibility that the results are due to chance and reduces the effect of flaws in the design of any one study. . . . [R]eplication is especially important for clinical studies of OTC analgesics because of the subjective nature of participants' responses and because of the presence of other variables which are difficult to quantify but could influence test results.

quirement was unprecedented but affirmed its appropriateness anyway.<sup>212</sup>

A potential softening of the two-test requirement for efficacy claims occurred when the Commission reconsidered several consent cases:

Recently the Commission has become aware of the existence of reliable expert opinion to the effect that one clinical study, if properly conducted, can provide a reasonable basis for future razor bump efficacy claims. Given the apparent conflict between the substantiation requirement contained in the orders and this expert opinion, the Commission believes that it is in the public interest to reopen the proceedings to examine whether one or two clinical tests is the proper reasonable basis standard. . . . [T]he Commission is seeking simply to put into effect the dictum expressed in *Pfizer* that the amount of evidence required to substantiate a claim can only be determined 'on a case-by-case basis.'<sup>213</sup>

Commissioners Pertschuk and Bailey dissented; Pertschuk objecting that "the costs of further review and introspection about the 'perfect' level of substantiation for this type of product far exceed any bene-fits."<sup>214</sup> Bailey noted that the presumed value of a second test was to correct unforeseen problems in the first test. Although the expert opinion held that one test would be sufficient *if* adequately conducted, Bailey said the majority's proposed change involved no more rigorous methodology. It involved only changing the word "two" to "one." "[T]he Commission," she said, "has not adopted . . . any new requirements to ensure that the single test can compensate for the absence of the second."<sup>215</sup>

Later the Commission declined to change the two-study requirement because:

[S]avings the company might achieve by conducting one fewer test appear modest since the relatively low cost of conducting a second test would not greatly exceed the cost of a single test that included additional procedural safeguards needed to enhance its reliability, such as those proposed by complaint counsel and the experts who commented. [R]espondent's past conduct ... of making false and unsubstantiated claims for its product on the basis of inadequate and flawed testing warrants imposition of a more rigorous substantiation requirement to provide additional assurance that the respondent will not engage in such conduct in the future.<sup>216</sup>

Meanwhile, the FTC required only one clinical study for efficacy

214. Id.

215. Id.

216. North Am. Philips Corp., McCaffrey & McCall, Sperry, DKG, 104 F.T.C. 549, (1984) (identical orders terminating show cause proceedings).

allowed. See supra text accompanying note 164. In General Nutrition (Commission opinion pending), the initial decision required one clinical study, with an FDA standard as alternative, for misrepresentations which were disease preventive claims rather than the more familiar curative or therapeutic (i.e., efficacy) claims. Dkt. 9175, F.T.C. slip op., at 106, 109 (Feb. 24, 1986).

<sup>212.</sup> Thompson Medical v. F.T.C., 791 F.2d 189, 193-96 (D.C. Cir. 1986).

<sup>213.</sup> North Am. Philips, McCaffrey & McCall (agency for Philips), Sperry Corp., DKG (agency for Sperry), F.T.C. slip ops. (Mar. 8, 1983) (identical show cause orders, never published).

claims in the *Braswell* hair restorative case.<sup>217</sup> Commissioner Bailey dissented on the ground of inadequacy.<sup>218</sup> Commissioner Pertschuk voted in favor, but cited reservations, including the objection that "the substantiation requirements are neither as tough as they ought to be . . . nor are they consistent with traditional Commission ad substantiation policy."<sup>219</sup> He cited the two-study standard of the FDA, and said "it is sensible and proper for the commission to look at the expert judgment of FDA for guidance in gauging what level of scientific substantiation to require."<sup>220</sup> The majority's rationale was not discussed in the Commission's brief statement.

## c. Discussion of Standards

The analgesics opinions discuss at length what constitutes an acceptable clinical test. That standards exist was well established in *American Home Products*: "[e]xperts in the field of clinical testing are generally agreed on the requisites of a well-designed clinical study."<sup>221</sup> Later, the Commission said it "[found] no reason to alter the decision we reached in [*American Home Products*] regarding the sort of evidence necessary to substantiate a claim of established superiority for analgesics."<sup>222</sup> Thompson Medical agreed. In that case, the respondent had argued that such a requirement should be relaxed or dispensed with for a mild and harmless topical analgesic. That, however, was declared contrary to the prevailing and accepted view: "A number of standards for an adequate and well-controlled clinical trial have been developed by the medical scientific community."<sup>223</sup>

A primary goal of standards is that "[p]re-existing bias toward the tested product on the part of the subjects or those involved in the execution of the study must be eliminated."<sup>224</sup> This is especially important with the tests in question: "Pre-existing bias toward the tested product is a particularly significant factor in working with OTC

224. American Home Prods., 98 F.T.C. at 376.

<sup>217.</sup> U.S. v. Braswell, No. C81-588A, slip op. (N.D. Ga. Sept. 14, 1983). See supra note 127.

<sup>218.</sup> Id.

<sup>219.</sup> Id.

<sup>220.</sup> Id.

<sup>221.</sup> American Home Prods. Corp., 98 F.T.C. 136, 376 (1981). The statement was cited with approval in the appeal, which upheld the F.T.C.'s findings that the tests and other evidence did not meet such requirements. American Home Prods. Corp. v. F.T.C., 695 F.2d 681, 691-93 (3d Cir. 1982).

<sup>222.</sup> Bristol-Myers, 102 F.T.C. 21, 332 (1983).

<sup>223.</sup> Thompson Medical Co., Inc., 104 F.T.C. 648, 720-21 (1984).

analgesics, which are readily identifiable by color, shape, or other distinctive attributes."<sup>225</sup> Bias may be eliminated by complying with various standards as discussed in the following subsections.

#### d. Double-Blinding

## A primary way to eliminate bias is that:

[T]he well-designed clinical study should be double-blinded—that is, neither the subjects nor those conducting the study should be able to identify the test drugs until preliminary analysis of the data is complete . . . The record shows that the expectations of both subjects and observers can affect the amount of relief obtained from the tested drug, and that this is a major source of bias in clinical testing.<sup>226</sup>

[N]either the test subject nor the person administering the test should be able to tell which treatment is being administered. . . . [I]t is important that the treatments all look and taste the same. If double-blinding is not used, subjects' responses may be influenced by their own pre-existing biases and by the expectations of those administering the tests.<sup>227</sup>

Bristol-Myers objected that double-blinding was not necessary, but offered no expert testimony to support its position.<sup>228</sup> It protested that double-blinding would "eliminate the actual and real clinical effect of expectation."<sup>229</sup> This was construed as an assertion that an analgesic works partly because the user believes it will work, and the respondent has a right to exploit that belief. However, "[t]he Commission cannot accept as proof of a product's efficacy a psychological reaction stemming from a belief which, to a substantial degree, was caused by respondent's deceptions."<sup>230</sup> The opinion added that "were we to hold otherwise, advertisers would be encouraged to foist unsubstantiated claims on an unsuspecting public in the hope that consumers would believe the ads and the claims would be self-fulfilling."<sup>231</sup>

Studies not double-blinded were downgraded in American Home

<sup>225.</sup> Id.

<sup>226.</sup> Id.

<sup>227.</sup> Bristol-Myers, 102 F.T.C. at 335. Further explanation was offered in Thompson Medical: "There is an important difference between a consumer's ability to perceive his pain relief and his ability to evaluate the true pharmacological efficacy of an OTC analgesic drug." Thompson Medical, 104 F.T.C. at 714. "Perceptions of performance are heavily influenced by expectations." Id. at 716. "[T]here is in fact no opportunity for usage to disconfirm consumer expectations, and each time consumers use Aspercreme they are reinforcing expectations they had when they came to the product in the first place." Id. at 717. Therefore.

<sup>[</sup>a]n analgesic trial should be double-blinded. . . . Effective blinding requires that neither the bottles, the physical characteristics of the test substance (such as taste and smell), nor the data sheet give any clue as to the identity of the substances used in the trial. Blinding both the subjects and the investigators is required. . . . Single-blind studies are not acceptable for mild to moderate analgesics.

Id. at 723.

<sup>228.</sup> Bristol-Myers, 102 F.T.C. at 335-36.

<sup>229.</sup> Id.

<sup>230.</sup> Id. at 336 (quoting Warner-Lambert Co., 86 F.T.C. 1398, 1496 (1975)).

<sup>231.</sup> Id.

*Products, Bristol-Myers*, and *Thompson Medical.*<sup>232</sup> Double-blinding was a problem in *Warner-Lambert*, where subjects in a study comparing Listerine to an inert substance may have been able to tell the difference because the latter simulated Listerine in color but not in taste or odor.<sup>233</sup> The doctor may have been able to detect the odor on subjects' breath.<sup>234</sup> The Commission observed that blinding the control group is a generally accepted procedure,<sup>235</sup> and that whatever bias the examiner may possess can be neutralized by preventing him from knowing which subjects used the product and which did not.<sup>236</sup>

e. Placebo Control

This is another type of control essential to clinical studies:

[T]he customary practice in drug comparison studies is to require a pharmacologically inactive treatment (placebo control) as a direct measure of test sensitivity. [If the drug tests no differently than the control the test is insensitive; it cannot measure the drug's effects (if any)]. Placebo control is particularly important in the case of analgesic studies because a subjective response like pain relief is highly susceptible to influence by the subject's expectations. . . . In clinical studies of mild to moderate pain, the rate of positive response to a pharmacologically inactive substance has been as high as 60% . . . The inert substance serves as a control for perceived pain relief based on expectations alone, or attributable to the self-limiting nature of mild to moderate pain.<sup>237</sup>

235. Id. at 1509.

236. Id. at 1510. The doctor knew the test was being conducted for Warner-Lambert, that it involved Listerine and that the data would be used to determine the effect on colds of gargling with Listerine daily. Id. at 1511. By using the same charts from day to day the doctor upon evaluating each subject's symptoms would know how he had evaluated them the previous day. Id. at 1512. On Mondays he made evaluations for Saturday and Sunday that could have been biased by being based on the nonblinded subjects' subjective evaluations. Id. In another study the investigators were found to have predetermined beliefs that Listerine was good for colds. Id. This and other criticisms of studies in Warner-Lambert were upheld on its appeal. Warner-Lambert v. F.T.C., 562 F.2d at 753.

237. American Home Prods. Corp., 98 F.T.C. 136, 377 (1981) (comment in brackets added). Elsewhere,

[i]n an analgesic trial, it is not appropriate to use "no treatment" as a control. Pain is a subjective sensation. . . . And the placebo effect is known to be substantial. . . . A placebo control is commonly required for a clinical trial of an analgesic drug in order to provide a consistent variable to determine whether a drug has a pharmacological effect. . . A placebo is particularly important in a study involving a drug for relief of pain because administration of a placebo produces a response that resembles the response to a mild analgesic.

Thompson Medical Co., 104 F.T.C. 648, 722 (1984). "A comparison of two drugs, one known to be effective, is termed a positive control.... If efficacy has not yet been es-

<sup>232. 98</sup> F.T.C. 136, 384 (1981); 102 F.T.C. 21, 342 (1983); 104 F.T.C. 648, 742-43, 827 (1984). A study cited in the latter had problems when subjects got headaches from the test agent's odor and bitter taste. *Id.* at 733.

<sup>233.</sup> Warner-Lambert, 86 F.T.C. at 1427, 1509.

<sup>234.</sup> Id. at 1511.

Placebo problems and blinding problems often occur together. A Warner-Lambert study had an ineffective placebo; the substance was inert but participants could differentiate it from Listerine.<sup>238</sup> Another study had no placebo, thus it compared Listerine's efficacy with nothing.<sup>239</sup> American Home Products, Bristol, Sterling, and Thompson Medical also criticized studies for no effective placebo control.<sup>240</sup>

#### f. Historical Control

While most controls are discussed for their applicability, the historical control was discussed for its inapplicability.

In circumstances involving diseases with high and predictable mortality and uniform symptoms, an historical control may be used, whereby the results of a new treatment are compared with case histories in similar patient populations

In an analgesic trial . . . the use of an historical control is not appropriate because there is no reason not to use a current control. . . . Moreover, since all pain is subjective and musculoskeletal pain fluctuates, use of an historical control for a drug like TEA/S is inappropriate.<sup>241</sup>

Bristol-Myers cited studies using an historical control, where subjects given Bufferin were asked to compare its side effects with those which they remembered to be associated with aspirin. "It is impossible," the opinion said, "to know whether the test subjects accurately remembered and related past experience with aspirin or whether they were able to distinguish the side effects caused by aspirin from side effects generated by other possible causes."<sup>242</sup>

Bristol-Myers Co., 102 F.T.C. 21, 335 (1983).

"[T]he placebo response rate is known to be always above zero in well-blinded studies." *Id.* at 180. *See also Sterling Drug*, 102 F.T.C. 395, 765 (1983).

238. 86 F.T.C. at 1509 (referenced in *American Home Prods.*, 98 F.T.C. at 377 n.30). 239. *Id.* at 1512.

240. 98 F.T.C. at 384; 102 F.T.C. at 180; 102 F.T.C. at 772; 104 F.T.C. at 743. The latter cited a study testing Aspercreme against an active control (aspirin), but not employing a third group using only placebo pills and placebo cream. *Id.* at 728.

Since there was no placebo control, there is no way to evaluate whether the methodology of this study was sufficiently sensitive to pick up even the known difference between aspirin and a placebo... Accordingly, there is no way to determine whether the study failed to show a difference between aspirin and Aspercreme because no real difference exists or because the methodology used was not sensitive enough to show a difference between the two.

tablished for the second drug, a placebo must be incorporated into the study design in order to demonstrate the sensitivity of the study's methodology." *Id.* at 728.

Whenever possible, tests comparing two mild analgesics should also compare those drugs against a pharmacologically inert placebo.... The use of the placebo provides a measure of the study's sensitivity; if the study cannot detect the difference between a standard and the placebo, it cannot be relied upon to detect the difference between the analgesics being tested.

Id.

<sup>241.</sup> Id. at 722.

<sup>242.</sup> Bristol-Myers, 102 F.T.C. at 342.

### g. Obtaining Statistical Significance

Another type of control is handled through determinations of statistical significance.

The statistical analysis serves to determine the probability that any apparent differences in efficacy are due to the treatments being tested and are not due to chance . . . . Scientists generally will accept the differences as being real and not due to chance if analysis shows a 95% level of statistical significance (i.e., there is no greater than a 5% likelihood that the results were produced by chance).<sup>243</sup>

Bristol-Myers called the 95% level arbitrary.<sup>244</sup> The opinion responded that such standard was selected not by the Commission but by scientists, and that among experts a consensus existed that the appropriate level was 95%.<sup>245</sup> Bristol-Myers also objected that scientists do not always submit comparative studies to statistical analysis. The decision conceded that scientists for some purposes do not test for significance, but that

[w]hen those same tests are used to establish the comparative superiority of one drug over another, it is essential to determine the statistical significance of the results. . . . If this is not done, it is impossible to reject the hypothesis that the drug which may appear superior in the test is, in fact, of only equal (or even lesser) effectiveness.<sup>246</sup>

Thompson Medical observed that a null hypothesis (that no difference exists between two tested items) cannot be proved true; statistics can only disprove the hypothesis or draw no conclusion:

A danger in evaluating clinical trials is to misinterpret a failure to demonstrate a difference between two treatments as meaning that the treatments are in fact the same. When differences are statistically significant, the results can be said to be due to essential differences in the drugs. When differences are statistically insignificant, however, this does not rule out the possibility that real differences may exist.<sup>247</sup>

Even when differences are statistically significant, they can be clinically insignificant.<sup>248</sup> Bristol-Myers stated that a determination must be made concerning whether a statistically significant difference is clinically significant; this will not be so if scientists regard the difference as too small to matter.<sup>249</sup>

249. 102 F.T.C. at 337.

<sup>243.</sup> Id. at 336. See also similar statements in American Home Prods., 98 F.T.C. at 377; Thompson Medical, 104 F.T.C. at 723-24.

<sup>244.</sup> Bristol-Myers, 102 F.T.C. at 337.

<sup>245.</sup> Id. "A lesser standard may be appropriate to support claims that have been adequately qualified or that are made to a limited audience capable of understanding levels of statistical significance." Id. at 337 n.54.

<sup>246.</sup> Id. at 336.

<sup>247.</sup> Thompson Medical, 104 F.T.C. at 724.

<sup>248.</sup> Id.

One improper procedure is "peeking" at the data. That is, the data are summarized not at the end of the study, but in small units each time more subjects are tested. By peeking after each such increment, American Home Products was able to order a study terminated when statistical significance had been reached in its favor.<sup>250</sup> Such "sequential analysis" could be legitimate if prior established procedures called for the study to stop when statistical significance was reached in favor of either possible conclusion. However, the ALJ concluded that this study would not have been stopped if significance were reached in favor of aspirin rather than Anacin.<sup>251</sup>

#### h. Protocol

The protocol is the document stating the testing procedures.

A written protocol which defines the study's objectives and methods is a critical element of a well-controlled trial. . . . The protocol should be written before the study is conducted. . . . It should describe the essential elements of the study design as well as the analysis plan, including the scoring system. . . . Departures from the protocol should be minimized to insure the validity of the ultimate analysis. . . . Any major change or amendment to the protocol should be in writing. . . . Data for a subject who breaches the protocol in a meaningful manner, by not taking the drug as directed or by otherwise acting inconsistently with the protocol is essential to protect the integrity of the study. . . . Selecting the statistical analysis and scoring system in advance guards against conscious or unconscious bias on the part of the investigator.  $^{252}$ 

A written protocol contributes to maintaining integrity in the testing procedures by encouraging strong suspicion of bias if subsequent deviation from the protocol occurs.<sup>253</sup> A similar deviation occurred in *American Home Products* where the protocol did not call for the "sequential analysis" discussed above, nor for termination of the study upon significance in AHP's favor.<sup>254</sup> *Sterling* discussed a study in which investigators changed their statistical method upon discovering that the original design would demonstrate no difference between Cope and aspirin. One expert called the study "a gross and obvious example of statistical manipulation, and . . . not acceptable scientific methodology."<sup>255</sup>

<sup>250.</sup> American Home Prods. Corp., 98 F.T.C. 136, 220-21 (1981). "Ongoing 'peeking' and evaluation of data by the party most interested in favorable results for one medication is generally recognized as injecting bias and necessitates a more critical review of the ultimate conclusions." *Id.* at 220.

<sup>251.</sup> Id. at 221. Bristol added that procedures for statistical analysis should be set forth in advance and adhered to in order to guard against bias caused by a premature conclusion when the data show a favored result. Bristol-Myers, 102 F.T.C. at 336.

<sup>252.</sup> Thompson Medical Co., 104 F.T.C. 648, 721-22 (1984). See similar statement in American Home Prods., 98 F.T.C. at 337.

<sup>253.</sup> Bristol-Myers, 102 F.T.C. at 334.

<sup>254. 98</sup> F.T.C. at 221.

<sup>255.</sup> Sterling Drug, Inc., 102 F.T.C. 395, 772 (1983).

Another study focused, in the original protocol, on pain relief generally, with no interest in specific body location.<sup>256</sup> That became a problem when the study was later used to support claims of pain relief in specific body areas. The study's original analysis had not separated weightbearing and nonweightbearing bodily areas, but an analysis three years later did so.<sup>257</sup> "Such *post hoc* analysis of clinical data calls into question the integrity of the result because of the potential bias present in any rearranging or manipulation of data  $\dots$ ."<sup>258</sup>

One study had no written protocol and inadequate records and analysis.<sup>260</sup> Another relied on subjective measures of pain, yet failed to report what questions patients were asked by doctors.<sup>261</sup> In another study the investigators were not provided with a uniform definition of a "cold." Common colds last no longer than ten days, yet illnesses lasting up to 69 days were counted as colds. In addition, the examining doctor spent only one and one-half minutes with each child. This may not have been an adequate amount of time.<sup>262</sup>

Sometimes protocols must be virtually identical:

It is also important in a multi-site study that the different investigators adhere to the same protocol. . . . [T]here is no assurance that the two physicians

260. Id. at 742-43.

261. Id. at 744.

<sup>256.</sup> Thompson Medical, 104 F.T.C. at 732.

<sup>257.</sup> Thompson Medical, 104 F.T.C. at 736.

<sup>258.</sup> Id. [citation omitted].

<sup>259.</sup> Id. at 736-37 [citation omitted]. The study had other protocol breaches. About 30% of subjects were outside the pre-specified age parameters. While the protocol required that subjects suffer moderate or severe pain, at least six of the forty had only mild to moderate pain symptoms. Id. at 733. Although departures should be minimized and major changes put in writing, the doctor made no written changes to the protocol. He testified that the protocol was subsequently amended orally, but was unable to recall any amendments. Id. In another study, several patients breached the protocol by applying the test cream twice rather than once. Since all were in the Aspercreme group and reported pain relief the question was raised of potential bias favoring Aspercreme. Id. at 739.

<sup>262.</sup> Warner-Lambert Co., 86 F.T.C. 1398, 1512-13 (1975).

applied the same criteria.... As of the time of Dr. Golden's deposition ... the two physicians had never even spoken to one another.... Dr. Altschuler ... was unaware that another investigator was conducting a trial with a protocol that was identical to his.<sup>263</sup>

## i. Choosing Subjects, Including Randomizing

A protocol should specify choice of subjects. *American Home Products* discussed the need for random distribution of subjects among treatment groups to balance out variables and biases not otherwise controlled.<sup>264</sup> Similarly:

There is virtually no disagreement that test subjects must be randomly assigned to the treatment groups... The purpose of randomization is to make certain that ... observed differences between treatment groups are attributable to the analgesics being tested and not to the inherent characteristics of the groups... Failure to randomize the test subjects renders questionable the validity of the study and all subsequent analysis ... although statistical techniques may be available to correct the imbalance if the importance of the imbalanced variable and the magnitude of the imbalance are not significant.<sup>265</sup>

Two studies lacked randomization.<sup>266</sup> One study used respondent's own employees, and allowed them to choose between using Listerine or nothing. This could have biased the results because those who thought gargling was effective for fighting a cold would most likely join the test group.<sup>267</sup>

Studies may likewise be inaccurate due to the failure to control characteristics of subjects. For example, a Bristol-Myers study involved baseline pain imbalance. Because response to medication is related to the starting level of pain, the greater the starting level, the more the opportunity for the pain to be relieved. More patients with severe initial pain were assigned to be tested on Excedrin, which meant that "Excedrin had a greater opportunity to relieve pain than did aspirin."<sup>268</sup>

Thompson Medical criticized a small sample for having an unacceptably wide array of conditions and diseases. With adequately sized subsets, comparisons could have measured the effects on persons suffering from each particular problem. But, lacking sufficient numbers in individual groups, the study could not provide a reasonable basis for efficacy claims concerning each specific condition.<sup>269</sup>

One analgesics study was conducted with only arthritis sufferers;270

<sup>263.</sup> Thompson Medical, 104 F.T.C. at 738-39 (citation omitted).

<sup>264. 98</sup> F.T.C. 136, 376 (1981).

<sup>265.</sup> Bristol-Myers Co., 102 F.T.C. 21, 334 (1983). See similar statement in Thompson Medical, 104 F.T.C. at 723.

<sup>266.</sup> Bristol-Myers, 102 F.T.C. at 342, 356.

<sup>267.</sup> Warner-Lambert, 86 F.T.C. at 1512.

<sup>268. 102</sup> F.T.C. at 347.

<sup>269.</sup> Thompson Medical, 104 F.T.C. at 731, 737.

<sup>270.</sup> Bristol-Myers, 102 F.T.C. at 342.

a second study failed to screen out aspirin non-responders and 18% of its subjects took concurrent analgesic, antirheumatic, or mood-altering drugs. Use of other medications concomitantly was deemed unacceptable in a noncrossover study. Moreover, because the subjects were given no washout period from pre-existing aspirin use, the researchers could not be sure what was measured.<sup>271</sup>

Pooling the subjects and data of separate groups was criticized as follows:

It is a requirement of a multi-site study that not only the same protocol be adhered to by all investigators, but also the patient groups be homogeneous in order that the data obtained from the different groups may be combined.... If the patients in the different groups are dissimilar or if they are being treated for different conditions, pooling the data is imappropriate.... [One study] provided mostly rheumatology patients while [the other] provided general medical patients.... [In the first study] thirty-two of the fifty patients (or 64%) self-rated their baseline pain as severe while only four of ... forty-five patients (or 11%) did so [in the second].<sup>272</sup>

Despite these differences, "the statistical analyses lumped the groups together."<sup>273</sup>

### j. Equivalence Requirements

A study must test exactly what the advertising claims:

[I]f the objective is to determine comparative drug efficacy, the tested products should be evaluated in the same study (together with a placebo). Without such head-to-head studies, the investigator is unable to determine whether products vary from each other to a significant degree.

[A]t least one of the required studies should be conducted on the type of pain for which the superior efficacy claim is being made. Because scientists do not fully understand the mechanism by which trauma evokes pain, they are not comfortable about extrapolating from one pain situation to another, or from experimental pain models, which employ artificially induced pain, to a clinical situation.<sup>274</sup>

One study examined, not headache pain, but two types of severe post-partum pain: uterine and episiotomy pain. American Home

<sup>271.</sup> Thompson Medical, 104 F.T.C. at 732-33. Another study had 10% of its subjects using anti-inflammatory or mood-altering drugs at the time of their participation, with no washout period. *Id.* at 739.

<sup>272.</sup> Id. at 738 (citations omitted).

<sup>273.</sup> Id.

<sup>274.</sup> American Home Products, 98 F.T.C. at 377-78. The same point was made in Bristol-Myers. See Bristol-Myers, 102 F.T.C. at 332-34 (according with American Home Prods. Corp., 98 F.T.C. 136, 334 (1981)). Bristol challenged the equivalence proposition, but had itself once argued that tests on subjects experiencing pain other than headache pain are not transferable. Bristol argued that studies cannot be conducted on headache pain, but six were mentioned in the record and one was expressly relied on by Bristol. *Id.* 

Products' witnesses admitted that headache pain is different from other kinds of pain. It is not known whether headache pain is a cramping pain, similar to uterine pain, or a constant pain, like episiotomy pain. Therefore, the study was rejected as not establishing Anacin's superiority over aspirin for relief of headache pain.<sup>275</sup> The general point was summarized in *Thompson Medical*: "[T]he use of the test drug should conform to reality. The test subjects should use the drug in the same manner as a consumer would in terms of dosage level, method of application, and the like .....<sup>276</sup>

As an obvious corollary, the medication tested must be the same as advertised. A study tested an aspirin-caffeine combination that was not equivalent to Anacin in its commercial form. It was not clear whether Anacin would achieve similar results.<sup>277</sup> Other studies compared Cope to aspirin while using a formulation of Cope which was different from the marketed version.<sup>278</sup> The same studies compared Cope against nothing but a placebo, which could not support Cope's superiority over other analgesics.<sup>279</sup>

Sterling Drug argued that the need for exact equivalence would mean testing Bayer against each of more than 200 brands; this would be prohibitively expensive. However, the Commission cited testimony that all brands might first be tested for pharmaceutical equivalence, as Sterling in fact had already done, and then clinical trials might be conducted on two or three brands to determine whether pharmaceutical differences correlated with therapeutic differences. If so, pharmaceutical equivalence could be assumed to mean clinical equivalence with very little testing.<sup>280</sup>

Bristol-Myers studies showed Bufferin absorbed into the bloodstream twice as fast as aspirin. However, there was no evidence of correlation between rate of absorption and the claimed speed of pain relief. Such equivalence may seem logical, but must remain a hypothesis until proven in clinical tests.<sup>281</sup>

<sup>275.</sup> American Home Prods., 98 F.T.C. at 381-83. Two studies in Bristol-Myers also involved only post-partum pain. 102 F.T.C. at 346-47. A study was rejected because it studied pain induced experimentally, results for which are not applicable to naturally occurring pain. *Id.* at 343. A study of aspirin use by potential stroke victims was held not relevant to the type of superiority claimed in Sterling Drug's ads. *See* Sterling Drug, Inc., 102 F.T.C. 395, 767 (1983).

<sup>276.</sup> Thompson Medical Co., 104 F.T.C. 648, 725 (1984).

<sup>277.</sup> American Home Prods., 98 F.T.C. at 382.

<sup>278.</sup> Sterling Drug, 102 F.T.C. at 771-72.

<sup>279.</sup> Id. at 772.

<sup>280.</sup> Id. at 769.

<sup>281.</sup> Bristol-Myers Co., 102 F.T.C. 21, 340 (1983); see also Sterling Drug, 102 F.T.C. at 765. Similarly:

<sup>[</sup>T]he record contains substantial medical-scientific evidence tending to show that two tablets of Anacin may reasonably be expected to provide technically greater analgesia than two tablets of aspirin for some individuals. However, that evidence is insufficient to overcome complaint counsel's *prima facie* 

Warner-Lambert cited a study in which Listerine was administered to animals. It was found not probative, particularly since the product was administered through stomach tubes rather than through gargling.<sup>282</sup> The Commission also criticized studies done in test tubes because they were not demonstrative of what occurs in the human mouth.<sup>283</sup>

A final equivalence issue involves the relationship of marketing information to advertising claims. The contention of consumer satisfaction, as derived by respondent from its surveys, cannot begin to approach in probative value the overwhelming weight of the expert testimony.<sup>284</sup> Thus,

[a] consumer may *perceive* a product to be effective when, in reality, it has no efficacy. In short, he may repeatedly purchase the product out of ignorance. . . Clearly, unless the patient can perform well-controlled clinical tests, he is not in a position to know whether his improvement was attributable to the medication.<sup>285</sup>

#### k. Expertise

Another necessary condition for an adequate test is the expertise of those who conduct it:

"[T]he investigator should generally be both experienced and independent. . . .

The persons who administer the test (be they medical personnel or the sub-

showing that the therapeutic superiority of Anacin over aspirin has not been established as a scientific proposition.

American Home Prods. Corp., 98 F.T.C. 136, 304-05 (1981).

AHP noted evidence that the dose response curve ascends, meaning pain relief increases as amount of aspirin increases. Therefore, it argued, because Anacin contains 150 mg. more aspirin per dose than common aspirin, it thus is shown to produce more pain relief. The argument was rejected because, *inter alia*, the curve rises little if any above 600 mg.; this does not prove superiority of 800 mg. over 650 mg. *Id.* at 383. The appellate court agreed. American Home Prods. Corp. v. F.T.C., 695 F.2d 681, 692 (3d Cir. 1982).

Thompson Medical observed that bioavailability is a necessary condition for bioactivity. Thompson Medical Co., 104 F.T.C. 648, 744-45 (1984). But evidence of bioavailability is not evidence of bioactivity. *Id.* at 726, 744-45. Thus, bioavailability studies are not a suitable substitute for clinical trials. *Id.* at 745, 773. In any event, studies showed that the blood level of analgesic achieved did not reach the minimum levels associated with analgesia, and that the drug was poorly absorbed and thus probably not bioactive. *Id.* at 749, 773.

Bristol-Myers observed: "The result of a bioassay is the 'relative potency' of the test drug." Bristol-Myers, 102 F.T.C. at 344. "Respondent has failed to distinguish between the two uses to which bioassays may be put. The primary purpose of a bioassay is dose selection. . . . Scientists normally do not use bioassays to compare the efficacy of analgesics." *Id.* at 345.

282. Warner-Lambert Co., 86 F.T.C. 1398, 1451, 1507 (1975).

283. Id. at 1444.

284. Id. at 1462.

285. Id. at 1495. For similar comments see Thompson Medical, 104 F.T.C. at 760.

jects themselves) should be adequately trained to assure accuracy in recording test results."  $^{286}\,$ 

"A clinical trial should be conducted by an experienced investigator with an appropriate background in the disease being evaluated.... The personnel who administer the test should also be experienced, as well as properly trained and instructed in using the measures involved in the clinical trial...."<sup>287</sup>

## 1. Prior Studies

An American Home Products study could not support advertising claims because it was conducted after the claims were disseminated.<sup>288</sup> Thompson Medical's reliance on an article describing test results was rejected because, although the article had been written long before, the respondent had not acquired it until after the claims were disseminated.<sup>289</sup>

Prior testing is not a scientific requirement, but relates to the legal conclusion that a violation occurs when claims are made without concurrent support. In 1984, the FTC declared that it *might* consider post-claim evidence, which it had previously refused to do. The FTC was not, it cautioned, offering advertisers a chance to substitute post-claim evidence, nor was it changing its holding that the lack of preclaim evidence creates a violation.<sup>290</sup>

- 2. Scientific Tests Generally
- a. Definitions

The general definition of "tests" is considerably broader than that for clinical tests. This is so because such tests cover a more expansive range of testing situations. While both clinical and nonclinical tests involve examining the characteristics of an advertised product, nonclinical tests do not examine consumer response to the product.

The early *Firestone* definition of "scientific test" has played a prominent role:

In our view a scientific test is one in which persons with skill and expertise in the field conduct the test and evaluate its results in a disinterested manner

- 287. Thompson Medical Co., 104 F.T.C. 648, 723 (citations omitted).
- 288. American Home Prods. Corp., 98 F.T.C. 136, 382, n.38 (1981).
- 289. Thompson Medical, 104 F.T.C. at 750.

General Nutrition is the first case to consider whether post-claim evidence can "shed light" on pre-claim substantiation. General Nutrition, No. 9175, F.T.C. slip. op. at 71-75, 78, 97-99 (Feb. 24, 1986).

<sup>286.</sup> Bristol-Myers Co., 102 F.T.C. 21, 334 (1983) (citations omitted).

<sup>290.</sup> Id. at 841; see also supra note 111. It will consider post-claim evidence when it wants to: (1) determine public interest—post-claim evidence that a claim is true might influence the Commission to decline to prosecute, not because a violation does not exist, but because of factors such as competing demands on scarce resources; (2) assess adequacy of prior substantiation—post-claim substantiation may shed light on the assessment of pre-claim substantiation, but will not substitute for it; and (3) determine scope of order—post-claim evidence of a claim's truth might lead to the framing of a narrower order. Id.

using testing procedures generally accepted in the profession which best insure accurate results. This is not to say that respondent always must conduct laboratory tests. The appropriate test depends on the nature of the claim made. Thus a road or user test may be an adequate scientific test to substantiate one performance claim, whereas a laboratory test may be the proper test to substantiate another claim. Respondent's obligation is to assure that any claim it makes is adequately substantiated by the results of whatever constitutes a scientific test in those circumstances.<sup>291</sup>

Later cases either cited the *Firestone* definition<sup>292</sup> or offered variations of it, when defining either a "competent and reliable test"<sup>293</sup> or "scientific or professional tests, analyses, research, studies, or any other evidence based on expertise of professionals in the relevant area."<sup>294</sup>

## b. Discussion of Standards

*Firestone* set a high standard when it debated whether to require "competent scientific tests" rather than merely "competent tests."<sup>295</sup> The conclusion was that "[i]n the circumstances of *this* case, . . . consumers could reasonably have expected Firestone's performance and safety claims to have been substantiated by scientific tests."<sup>296</sup> The tests for tire stopping ability were inadequate because they involved

294. Blue Lustre, No. C-3195, F.T.C. slip op. at 3 (1986); Sunbeam No. C-3181, F.T.C. slip op. at 3 (1986); North Am. Philips, No. C-3180, F.T.C. slip op. at 5 (1986); Young & Rubicam/Zemp., 105 F.T.C. 317, 339 (1985) (agency for Rush-Hampton); Rush-Hampton, No. 9167, F.T.C. slip op. at 5 (1985); Associated Mills, 106 F.T.C. 5, 23 (1985); P. Leiner Nutritional Prods., 105 F.T.C. 291, 301 (1985); Adria, 103 F.T.C. 512, 526 (1984); FC&B, 102 F.T.C. 1274, 1283 (1983) (agency for Amana); Amana Refrigeration, Inc., 102 F.T.C. 1262, 1267 (1983); Merideth, 101 F.T.C. 390, 405 (1983).

295. Firestone, 81 F.T.C. at 426-27.

296. Id. at 463. The action was upheld without specific discussion of the nature of tests. 481 F.2d at 251. See also supra text accompanying note 291.

<sup>291.</sup> Firestone Tire & Rubber Co., 81 F.T.C. 398, 463 (1972), aff'd sub nom., Firestone v. F.T.C., 481 F.2d 246 (6th Cir. 1973).

<sup>292.</sup> General Motors, and its agency, Campbell-Ewald, 104 F.T.C. 511, 513, 516 (1984) (Firestone definition plus sentence about handling tests); Teledyne, Inc., 97 F.T.C. 320, 330 (1981) (almost exact restatement of Firestone's first sentence); Crown Central Petroleum, 84 F.T.C. 1493, 1549 (1974).

<sup>293.</sup> National Energy Associates, No. C-3179, F.T.C. slip op. at 8 (1986); Cynex Mfg. Corp., 104 F.T.C. 464, 475 (1984); Cliffdale Ass'n, Inc., 103 F.T.C. 110, 199 (1984); California-Texas Oil, 104 F.T.C. 268, 278 (1983); Monte Proulx, 102 F.T.C. 1722, 1726 (1983); Emergency Devices, Inc., 102 F.T.C. 1713, 1717 (1983); Plaskolite, Inc., 101 F.T.C. 344, 349 (1983); Champion Home Builders, 101 F.T.C. 316, 322 (1983); Boekamp, 97 F.T.C. 291, 314 (1981); Energy Efficient Systems, 97 F.T.C. 265, 273 (1980); Sears, Roebuck & Co., 95 F.T.C. 406, 524 (1980); Montgomery Ward & Co., Inc., 95 F.T.C. 265, 273 (1980); C.I. Energy Dev., Inc., 94 F.T.C. 137, 1359 (1979); RR Int'l, Inc., 94 F.T.C. 1312, 1334 (1979); Gordon Cooper, 94 F.T.C. 674, 696 (1979); Thompson, 94 F.T.C. 331, 339 (1979) (agency for Sears, Roebuck & Co.); Norris, 92 F.T.C. 989, 1015 (1978).

only one road surface, albeit a hazardous one.<sup>297</sup> One test surface, similar to "glare ice," was not typical of roads in the United States, and a tire's performance relative to other tires can vary from one surface to another.<sup>298</sup> Thus, there was not an adequate sampling of possible conditions.

Further, Firestone's ads for "The Safe Tire," by stressing exacting, rugged tests "far exceeding any driving conditions" consumers will ever encounter, constituted a representation that Firestone tires would be absolutely safe, and that the company could assure that its tires were free from any defects.<sup>299</sup> But the company had stipulated that "[t]he state of tire manufacturing technology is such that use of the best manufacturing procedures and tests and quality control techniques known to the industry cannot insure that each tire ... is absolutely free from any defects ... .<sup>300</sup> Therefore, the tests were inadequate not only because they did not demonstrate absolute safety, but because they could not possibly do so.<sup>301</sup>

Sun Oil faced an equivalence problem when it showed that Sunoco contained more phosphorus than some competitors, but offered no performance tests that compared Sunoco with competing brands containing less phosphorus.<sup>302</sup>

Sears did much to develop the requirements of scientific tests. Although Sears

was not required to have had as substantiation 'scientific' tests, to the extent Sears relied on tests, they were required to be competent and reliable . . . [meaning they] had to truly reflect the universe of food soils encompassed by Sears' unqualified representation [that no pre-scraping or pre-rinsing were necessary before dishwashing].<sup>303</sup>

### Also, competent and reliable tests would have to

demonstrate that consideration had been given . . . to the many variables which affect the cleaning performance of Sears' dishwashers. Among these factors . . .: detergent used and amount, voltage, mechanical function of dishwasher, number of washes and rinses and their precise duration, water temperature, water hardness, type and number of cooking and eating dishes washed, loading of dishwasher, food soils used, method of food preparation and soiling of dishes, counteraging, cooking temperatures.

The foregoing are illustrative only and are listed simply to provide an indication of the factors competent and reliable tests should have given considera-

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<sup>297. 81</sup> F.T.C. at 449.

<sup>298.</sup> Id. at 445.

<sup>299.</sup> Id. at 452.

<sup>300.</sup> Firestone Tire & Rubber Co. v. F.T.C., 481 F.2d 246, 249 (6th Cir. 1983).

<sup>301.</sup> Firestone, 81 F.T.C. at 457.

<sup>302.</sup> Sun Oil, 84 F.T.C. 247, 272 (1974). A similar situation arose in *Standard Oil* where the company was charged with claiming its gasoline would completely eliminate all pollutants. Not only did the tests fail to examine all pollutants, they also failed to support the claim for the ones they did examine. Standard Oil of Calif., 84 F.T.C. 1401, 1465, 1468 (1974). "Complaint counsel's major challenge to the Scott tests is aimed not at whether the tests were properly conducted in a technical sense, but whether the tests really show what respondents' advertisements say they do." *Id*. at 1467.

<sup>303.</sup> Sears, Roebuck & Co., 95 F.T.C. 406, 423 (1980).

tion to in determining, prior to dissemination of the representation, whether or not the Sears' dishwashers would perform in accordance with the representation.

Competent and reliable tests should have included information as to the scoring procedure used and the analysis of the results. Records should have been kept in sufficient detail so that the tests could be conducted again, and similar results obtained.<sup>304</sup>

The litany of Sears' failures on these criteria is far too extensive for inclusion here. $^{305}$ 

In *Cliffdale*, consumer tests provided no basis for fuel economy claims.<sup>306</sup> Consumers made subjective judgments for which reproducibility was low, and measured fuel consumption merely by topping their tanks.<sup>307</sup> This illustrated that consumers respond to the Hawthorne effect: they alter their habits when knowing they are in a test situation.<sup>308</sup> Many variables that affect fuel consumption are uncontrolled in consumer tests.<sup>309</sup> Meanwhile, independent laboratory testing showed benefits nowhere near the levels claimed.<sup>310</sup>

The requirement that tests be conducted by "persons qualified to do so" has appeared in several provisions beginning with Amana.<sup>311</sup>

304. Id.

Sears claimed that a test should be discounted for creating abnormal conditions by using foods especially prepared to stick to dishes. The ALJ rejoined that Sears' advertisements were expressly designed to convince the public that the dishwasher could remove the most difficult foods. *Id.* at 427, 428.

307. Id. at 143.

308. Id.

<sup>305.</sup> For example, failures occurred in those situations where: the tests used foods relatively easy to clean, id. at 429, 434, 436; the tests used higher water temperatures and lighter loads than many consumers would use, id. at 430; the wash phase extended beyond length available to consumers, id. at 430, 432; the detergent used was in excess of recommended amount, id. at 436; water softener was used, but not mentioned in test reports, id. at 469; the dishes were placed flat, although consumers typically tilt them at an angle, id. at 430; only a sample, rather than all dishes, was inspected, although advertising claimed all dishes would be cleaned, id. at 438; the results were assessed on the basis of photos of the dishes rather than the actual dishes, id. at 465-66; actual dishes were introduced as evidence, but not examined at the end of the wash cycle, id. at 466; despite such conditions favoring dishwasher, tests not only failed to support, but actually refuted, claims of no pre-rinsing or pre-scraping and that the upper rack cleaning ability was as good as lower rack, id. at 427, 445, 459, 465, 470, 514; tests of different brands were offered as evidence of performance of the Sears' brand, id. at 434; claim of eliminating bacteria was based on no tests, id. at 476; knowledge from Sears' own market research that many consumers rejected the claims after using the dishwasher, id. at 452, 514; Sears' counsel improperly participated in allegedly impartial tests, id. at 467; and inadequate record keeping: information missing, replication impossible, Id. at 430, 433, 436, 438.

<sup>306.</sup> Cliffdale Assoc., Inc., 103 F.T.C. 110, 153 (1984).

<sup>309.</sup> Id. at 152.

<sup>310.</sup> Id. at 139.

<sup>311.</sup> Amana Refrigeration, Inc., 102 F.T.C. 1262, 1266 (1983).

This replaced requirements for qualifications such as expertise or experience in the given field. Although no explanation has been given for this change, it is likely that *Litton*, which involved surveys rather than tests, was influential.<sup>312</sup>

### B. Surveys

While this section discusses surveys explicitly, many of the points about clinical tests apply by analogy to surveys, since observing samples of people is common to both. Order provisions dealing with surveys tend to be worded to forbid surveys lacking certain specifications. For that reason, some of the cases in this section have not been discussed earlier.

## 1. Definition and Discussion of Standards

Only *Litton* has offered a definition of an adequate survey: "[a] competent and reliable survey means one in which persons qualified to do so conduct the survey and evaluate its results in an objective manner, using procedures that insure accurate and reliable results."<sup>313</sup> The phrase "persons qualified to do so" was not as strong as complaint counsel had requested. Counsel had wanted to require an "expert," but the Commission thought that standard would be too inflexible. In addition, this standard would unnecessarily preclude the legitimate use of persons with no professional expertise in certain aspects of a survey project, such as interviewing.<sup>314</sup>

The Commission stressed Litton's admission that its surveys had originally been intended only for internal company use. Surveys used in advertisements should be conducted under stricter standards than those conducted solely for internal use.<sup>315</sup>

<sup>312.</sup> Litton Indus., Inc., 97 F.T.C. 1 (1981), modified, Litton Indus., Inc. v. F.T.C. 676 F.2d 364 (9th Cir. 1982), modified order, 100 F.T.C. 457, 458 (1982). See infra text accompanying notes 313-14.

<sup>313.</sup> Litton, 100 F.T.C. at 458.

<sup>314.</sup> Litton, 97 F.T.C. at 74-75. The appellate court approved the phrase "persons qualified to do so." Litton, 676 F.2d at 373.

<sup>[</sup>T]he degree of experience and expertise required ... must inevitably depend upon the circumstances... Certain expertly designed surveys can obviously be conducted by lay personnel, with no survey expertise... Indeed, it is possible that some types of surveys might be so simple that relatively little or no specialized training would be necessary even to design them. Most often, however, surveys or tests, to be competent and reliable, will require at least some expert input at the design stage.

Litton, 97 F.T.C. at 75.

<sup>315.</sup> Litton, 97 F.T.C. at 73. Surveys for internal use may have lesser standards and still be acceptable because the users are aware of the defects and equipped to assess them. A consumer, however, could not adequately assess the deficiencies. *Id*.

The existence of a 'survey' as support for a claim of product superiority may well imply to many consumers a measure of precision and accuracy that they would be less willing to attribute to the same claim made without reference to

### 2. Improper Design or Execution

Improper features make surveys incapable of producing valid findings. To cite such a survey as inadequate appears equivalent to charging that it cannot be used as a reasonable basis. The order provisions seen here, however, are not worded to forbid the survey-based claim unless a reasonable basis exists; rather, they forbid the claim unless the improper survey feature is eliminated.

One type of improper feature involves samples unrepresentative of the claimed population. The complaint in *Teledyne* charged that a survey of dentists was inadequate to support claims for the Water Pik oral irrigating device. Teledyne was ordered to:

cease and desist from . . . [e]mploying, in any advertisement for any product, the word "survey" (or any comparable term), or basing any claim upon one or more surveys in whole or in part which states, either expressly or by implication, the beliefs, opinions, practices, recommendations, or endorsements of any group, unless . . . a representative, unbiased and fair sampling from the population referred to in the advertisement is questioned . . . [and] the survey was designed, executed and analyzed in a competent and reliable manner.  $^{316}$ 

Litton was ordered to cease "[a]dvertising the results of a survey unless the respondents in such survey are a census or a representative sample of the population referred to in the advertisement."<sup>317</sup> The provision resulted from improper methodology in surveying independent microwave oven service technicians who serviced Litton and at least one competitor.<sup>318</sup> The sample actually compiled was of service agencies, with the stated intention of choosing one technician at each sampled agency. However, there was no random selection of technicians at given agencies. In some cases, a manager was chosen rather than a technician.

Also, the sample consisted only of agencies that had "Litton-authorized" technicians, even though at least one hundred additional

318. Litton, 97 F.T.C. at 70-78.

any statistical support. We assume this is why advertisers wish to use surveys

Id. at 72.

<sup>316.</sup> Teledyne, Inc., 97 F.T.C. 320, 329 (1981). Teledyne's agency, Thompson, received an order that was similar but referred to a "projectable" sample. J. Walter Thompson Co., 97 F.T.C. 333, 334 (1981) (consent order).

<sup>317.</sup> Litton, 100 F.T.C. at 459. "A representative sample need not be a probability sample so long as when the ad is first disseminated respondents have a reasonable basis to expect the sampling method used would not produce biased results." *Id.* "A representative sample . . . is [one] that has been selected in a manner which permits projection of results from the sample to the universe from which it is drawn." *Litton*, 97 F.T.C. at 76 n.11. The appellate court upheld the use of the term "representative sample," calling it sufficiently clear and specific. *Litton*, 676 F.2d at 372.

agencies fit the stated criterion of having technicians that serviced Litton and at least one competitor. Litton claimed it could not get lists of non-Litton-authorized technicians. However, the evidence showed it was aware of many such persons. Technicians in non-Litton-authorized agencies might have answered less in favor of Litton when asked what microwave ovens they preferred. Further, a number of service agencies that *were* sampled were found inappropriate because they were also dealers (which is bias-producing),<sup>319</sup> or no longer in business, or not actually servicing Litton and at least one other brand. Litton did not help its case when it conceded that its original intent had been to get an entire census and not just a sample.

The Commission concluded that Litton's knowledge of these defects, prior to running the advertisements, meant Litton knew that the surveys provided no reasonable basis.<sup>320</sup> The FTC's counsel came close to establishing additional points of error.<sup>321</sup> Although they tried to show that more agencies than the identified hundred could have been included in Litton's sample, they failed because a survey done for them by Chilton Research was disregarded as not useful.<sup>322</sup> They also questioned whether the surveys were conducted independently of Litton's influence, but the initial decision concluded there were elements of both independence and dependence, and consumers would not expect full independence.<sup>323</sup>

Counsel also claimed that the population which consumers would see referenced would be *all* of the independent microwave oven service technicians, including those not servicing Litton at all.<sup>324</sup> This was rejected in the initial decision even though some of Litton's ads might be read as referring to all technicians.<sup>325</sup> The Commission agreed with the initial decision on the grounds that the additional deception of consumers who made such assumption would be very little.<sup>326</sup>

*Litton* served as sounding board for many efforts by complaint counsel to limit use of surveys. The initial decision said that the proposals tended to assume that "there are clearly defined and generally accepted procedures in the market research field, which must be fol-

<sup>319. &</sup>quot;Respondent's own experts have shown that the answers of a servicing dealer would tend to be biased in favor of a brand which it sells, and that such agencies should not be included in a survey for that reason." *Id.* at 28. *See also infra* text accompanying note 346 for a discussion of improper handling of experts.

<sup>320.</sup> Litton, 97 F.T.C. at 80.

<sup>321.</sup> Id. at 33-36.
322. Id. at 36-39.
323. Id. at 22-23.
324. Id. at 33.

<sup>325.</sup> Id. at 33 n.17.

<sup>326.</sup> Id. at 70 n.5.

lowed if a survey is to have any validity."<sup>327</sup> It concluded that the evidence did not support this position because Litton had presented unrebutted testimony that there was no such single body of generally accepted principles. Since the proposals were so innovative, they should be given affirmative support on the record rather than merely urged.<sup>328</sup> The Commission's opinion did not disagree with this finding. Because of such extensive discussion, *Litton* stands as the key expression of the FTC's approach to surveys.

Kroger, the grocery chain, was given the following order:

cease and desist from advertising any survey-based food price comparison that refers, directly or indirectly, to a particular city, metropolitan area or competitor (or competitors) by name or other designation unless . . . [e]mployees responsible for pricing . . . [Kroger's] merchandise do not know which items have been selected for the survey prior to its completion . . . .<sup>329</sup>

Kroger claimed that its surveys constituted proof of pricing claims, and therefore implied they were methodologically sound.<sup>330</sup> However, the sample was not representative of, nor projectable to, the total population of Kroger's prices. The person who selected the sample items in each marketing area was also the person who set prices in that area. That person systematically chose items that Kroger was getting from manufacturers on special promotion. Thus, the products could be sold at reduced prices. A survey that Kroger conducted separately for its own internal use, which lacked such defects, showed Kroger to have higher prices than indicated by the advertised survey.<sup>331</sup>

American Home Products advertised that twice as many specialists in internal medicine preferred Anacin for headache pain to any other nonprescription internal analgesic, and that more physicians recommended Anacin for headache pain than any other comparable product. In addition, American Home Products alleged that these facts,

331. Id. at 741-44. The original order was more specific: the items used had to be randomly selected from the population of products to which the results would be generalized, and the items had to be representative of the population. Id. at 773. The comparisons had to be of identical or substantially similar items. These specifications were removed in the modification, with no explanation appended. But see 100 F.T.C. at 575 (Pertschuk, Comm'r, dissent). The modification was made after the arrival of Chairman Miller, who generally supported lesser degrees of regulation.

<sup>327.</sup> Id. at 50.

<sup>328.</sup> Id.

<sup>329.</sup> Kroger Co., 98 F.T.C. 639 (1981), modified, 100 F.T.C. 573, 574 (1982) (modified following internal reconsideration).

<sup>330.</sup> Kroger, 98 F.T.C. at 732. "Since I do not read the advertisements to contain such implied claims, I would dismiss the complaint." *Id.* at 769 (Bailey, Comm'r, dissenting).

as demonstrated by a mail survey, constituted proof that Anacin is more effective. It was determined that the survey was inadequate because it sampled only physicians with a primary specialty in internal medicine who were in private practice and willing to receive promotional mail.<sup>332</sup>

A second improper feature of a survey is a sample that is too small to allow projections to the population. Teledyne was ordered to do the following:

cease and desist from . . . [e]mploying, in any advertisement for any product, the word 'survey' (or any comparable term), or basing any claim upon one or more surveys . . . unless . . . a projectable sample was used and the sample size of and the response rate to the survey were sufficiently large so as to allow meaningful projections to the population referred to in the advertisement with a reasonable degree of confidence, unless there is a clear and conspicuous disclosure in the advertisement that the survey may not be representative of the population referred to in the advertisement  $\ldots$ .<sup>333</sup>

The next improper feature was an unacceptably small response rate. The *Teledyne* provision relates to this problem as well. Also, American Home Products, along with an unrepresentative sample, had a response rate that was only 10%.<sup>334</sup> Finally, there is the improper feature of using survey results so old that the opinions of those surveyed may have changed. Teledyne was ordered to do the following:

cease and desist from ... [e]mploying, in any advertisement for any product, the word 'survey' (or any comparable term), or basing any claim upon one or more surveys ... unless ... the survey was completed within three (3) years prior to the date of the representation, unless there is other appropriate data which establish a reasonable basis for concluding that the beliefs, opinions, practices, recommendations or endorsements of the members of the group referred to in the advertisement have not materially changed since the completion of the survey ...  $^{335}$ 

#### C. Summary

As this section has illustrated, the FTC has imposed professional standards upon advertisers whose treatment of tests and surveys was not up to professional expectations. In approximately fifteen years the Commission has raised the standards of the marketplace to high levels from a starting point that involved virtually no guidance whatsoever. One might observe that the basic guidance of the prohibition against deceptiveness was always present. However, to replace the statutory vagueness with the precision of the prescriptions just seen

<sup>332.</sup> American Home Prods. Corp., 98 F.T.C. 136, 182, 395 (1981). Respondent was given an order provision described under General Misrepresentation Provisions. See infra text accompanying note 352.

<sup>333.</sup> Teledyne, Inc., 97 F.T.C. 329 (1981). The order to the agency was substantively the same. Id. at 334.

<sup>334.</sup> American Home Prods. Corp., 98 F.T.C. at 182, 395.

<sup>335.</sup> *Teledyne*, 97 F.T.C. at 329. The order to the agency was substantively the same. *Id.* at 334.

constitutes a monumental change in the orientation given by a governmental body whose Congressional mandate, after all, is to prevent violations rather than punish violators.

### X. Additional Provisions Regarding Tests and Surveys

This section takes up issues beyond the "mainstream" topic of misrepresentation of tests and surveys as substantiation for claims. The issues discussed in this section represent significant additions to that fundamental topic.

#### A. Overclaiming of Results

Thus far, the order provisions have reflected an absence or inadequacy of evidence. Another factual situation arises when the evidence is adequate for certain claims, but the advertiser has made stronger claims which the evidence cannot support. For practical purposes the outcome is the same: the claim is prohibited unless substantiation becomes available. However, after several early cases, a distinct form of order provision was designed for this particular problem.

In *Firestone*, the FTC did not declare respondent's stopping tests inadequate or unscientific for all claims, but stated that, "The practice of respondent being challenged here was not in the design of its particular test but in its failure to limit its advertising claim to the type of comparative tire performance which its test results substantiated."<sup>336</sup>

General Motors was the first to receive a provision aimed specifically at overclaiming. Its Cadillac Eldorado was claimed to be proved superior in gasoline mileage to many competitors, whereas in truth it was superior only to some. The company was told to cease the following:

[r]epresenting . . . by reference to a test or tests, that any of respondent's automobiles is superior with regard to fuel economy to any other automobiles, whether manufactured by respondent or others, unless: (a) such superiority

<sup>336.</sup> Firestone Tire & Rubber Co., 81 F.T.C. 398, 449 (1972), aff'd, Firestone v. F.T.C., 481 F.2d 246, 251 (6th Cir. 1973). The provision was the one seen earlier, which did not address overclaiming specifically. See supra note 112 and accompanying text. See also discussion supra text accompanying notes 297-98. See also Ford Motor Co., 84 F.T.C. 729 (1974) and J. Walter Thompson, 84 F.T.C. 736 (1974) (an automobile was proved quieter than an airborne glider, but this did not prove the automobile was quiet); Standard Oil Co. of Cal., 84 F.T.C. 1401 (1974); Crown Central Petroleum Corp., 88 F.T.C. 210 (1976) (automobile pollution was proved to be reduced somewhat; however, there was no evidence for the claimed complete reduction).

has been demonstrated, as to the model(s) for which it is claimed, by such test or tests with respect to each sample, or the valid average of all identical samples, of each model represented to have been tested; or (b) the valid test results for each sample, or the valid average of all identical samples, of each model so compared, including the advertised model as well as such makes and models to which the advertised model is compared, are clearly and conspicuously disclosed.<sup>337</sup>

Advertisers of acne preparations had tests of bacteria being killed, but overclaimed the relationship to acne.<sup>338</sup> Contraceptives had novel delivery characteristics, but that did not mean they had superior effectiveness.<sup>339</sup> In the event that dynamometer tests would be used in the future as support for claims,<sup>340</sup> the FTC undertook to prevent possible overclaiming by requiring the following in *Cliffdale*:

[r]espondents shall, when using the results of any tests required, clearly and conspicuously disclose the limitations upon the applicability of the results to any motor vehicle. Where the results of such tests are used in connection with a representation of fuel economy improvements expressed in miles per gallon (or liter), miles per tankful, or where the representation of the benefit is expressed as a monetary saving in dollars or percentages, all advertising and other sales promotional materials that contain the representation must also clearly and conspicuously disclose the following disclaimer: 'REMINDER: Your actual saving may vary. It depends on the kind of driving you do, how you drive and the condition of your car.'<sup>341</sup>

The FTC ordered Kroger to do the following:

cease and desist from advertising any survey-based food price comparison that refers, directly or indirectly, to a particular city, metropolitan areas or competitor (or competitors) by name or other designation unless . . . [t]he claim does not generalize the results of the survey to a product category that has been systematically excluded therefrom; provided, however, that no such generalization will be deemed to extend to any product category whose systematic exclusion is disclosed clearly and conspicuously in . . . advertisements.<sup>342</sup>

Kroger had limited its surveys to dry groceries, yet advertised them as applying to all food categories. In truth, Kroger compared favorably to its competitors for dry groceries, but not for meat and produce. A separate set of surveys, conducted for internal use, which included meat and produce, showed Kroger had prices higher overall. Although this may appear to illustrate improper sampling, it is not

<sup>337.</sup> General Motors Corp., 84 F.T.C. 653, 660 (1974). "Sample" was defined to mean "an actual automobile tested." *Id.* Matsushita and Chrysler had similar facts and similar provisions. Matsushita Elec. Corp. of America, 89 F.T.C. 157, 162 (1977) (consent); Chrysler Corp., 87 F.T.C. 719 (1976), modified, Chrysler Corp. v. F.T.C., 561 F.2d 357 (D.C. Cir. 1977), modified order, 90 F.T.C. 606, 606 (1977).

<sup>338.</sup> Karr Preventative Medical Prods. Inc., 94 F.T.C. 1080, 1091 (1979); National Media Group, Inc., 94 F.T.C. 1096, 1107 (1979).

<sup>339.</sup> American Home Products, 95 F.T.C. 884, 894 (1980); Sorga, 97 F.T.C. 205, 215 (1981).

<sup>340.</sup> See supra note 118.

<sup>341.</sup> Cliffdale Ass'n, 103 F.T.C. at 199-200.

<sup>342.</sup> Kroger Co., 100 F.T.C. 573, 574 (1982). Other cases of overclaiming include the following: General Elec. Co., 89 F.T.C. 209, 217-18 (1977); Standard Brands, Inc., 97 F.T.C. 233, 242-43 (1981). Ted Bates, 97 F.T.C. 220, 229-30 (1981). The advertisements involved only surveys, not tests, but the provisions cited both.

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impermissible *per se* to exclude certain categories. What is wrong is to make claims as though they were not excluded.

### B. Underclaiming of Results

In two survey cases order provisions were directed against suppression of findings that, if known to consumers, would create a lower regard for the revealed findings. Standard Brands claimed that "twice as many doctors choose Fleischmann's as any other brand." However, the ads did not reveal that at least 67.5% of the sampled doctors, when asked what brand they would recommend, recommended no specific brand name. Thus, although the claim was true for those who *did* name a brand, only 15.5% of the total recommended Fleischmann's.<sup>343</sup>

Amana was charged with representing that its microwave ovens and those of five competitors were given four tests, with only Amana passing all four, whereas in fact the tests had involved six competitors and the sixth had also passed all four. The complaint also charged that, although many owners of other brands rated Amana as having the "best quality," they also rated their own brand that highly as often or more often. Further, the vast majority of owners of other brands did not rate Amana "best quality." And, although owners of nine competitors were surveyed, Amana reported results regarding only four of them.<sup>344</sup>

#### C. Misrepresentations About Experts

Advertisements may misrepresent the expertise of those who conducted the tests.<sup>345</sup> Moreover, they may misrepresent surveys of people whose presumed expertise will enhance the value of claims. Many of Litton's survey respondents were not experts.<sup>346</sup> Teledyne's survey of dentists did not amount to surveying their professional or-

<sup>343.</sup> Standard Brands, 97 F.T.C. at 242. Ted Bates, 97 F.T.C. at 229.

<sup>344.</sup> Amana Refrigeration, Inc., 102 F.T.C. 1262, 1265 (1983) (two provisions); FC&B (agency for Amana), 102 F.T.C. 1274, 1282 (1983) (two provisions).

<sup>345.</sup> Kenrec Sports Inc., 80 F.T.C. 868, 872 (1972); Nu Dimensions Int'l Ltd., 81 F.T.C. 793, 803 (1972); Le Conte Cosmetics Inc., 87 F.T.C. 1348, 1355 (1976); Weider, 106 F.T.C. 584, 598 (1985) (all consent).

<sup>346.</sup> Litton Indus., Inc., 97 F.T.C. 1, 72 (1981). The order defined "expert" as "an individual, group or institution held out as possessing, as a result of experience, study or training, knowledge of a particular subject . . . superior to that generally acquired by ordinary individuals." *Litton*, 100 F.T.C. at 459.

ganization.<sup>347</sup> Similarly, doctors commenting on brands of margarine were not experts on those product types.<sup>348</sup>

# D. Consumer Endorsements or Testimonials Related to Tests or Surveys

Standard Brands included a statement that "[a]n advertising claim which is a personal endorsement of a product reflecting solely the subjective opinion of the endorser shall not be deemed to be a test."<sup>349</sup> In other cases, however, endorsements or testimonials have been regarded as implying that they were supported by tests, and were forbidden unless so supported.<sup>350</sup> Were such tests available, the advertiser probably would prefer to devote his advertising space to them rather than to endorsements. Therefore, such provisions appear to rule out endorsements or testimonials in situations where claims can be substantiated only by scientific or medical tests.

Endorsements or testimonials by consumers may impliedly misrepresent that they are representative of the public at large. The FTC makes no charge that the advertiser had conducted a survey improperly, or conducted a survey at all, but rather that such endorsements or testimonials give the misleading impression of applying to that wider public. Since that is similar to the impact of a survey, provisions forbidding it are cited here.<sup>351</sup> The use of a single endorser has been known to produce violations, as when astronaut Gordon Cooper

Cooga-Mooga was also ordered to disclose any familial connection between endorser (entertainer Pat Boone) and advertiser (Boone was president). *Cooga Mooga*, 92 F.T.C. at 321, *modified*, 98 F.T.C. at 816.

Cliffdale was also ordered not to use outdated endorsements. *Id.* In addition, it was ordered to disclose any connection between endorsers and respondents that might affect credibility and would not be otherwise known to consumers. *Id.* 

Several respondents were ordered to use no endorsements absent written authorization within twelve months from the person or organization: American Consumer, 94 F.T.C. at 661; Cooper, 94 F.T.C. at 696; RR Intl, 94 F.T.C. at 1334; C.I. Energy, 94 F.T.C. at 1359; Ball-Matic Corp., Inc., 98 F.T.C. 836, 853 (1981).

<sup>347.</sup> Teledyne, Inc., 97 F.T.C. 320, 329 (1981); J. Walter Thompson Co., 97 F.T.C. 333, 334 (1981).

<sup>348.</sup> Standard Brands Inc., 97 F.T.C. 233, 242-43 (1981); Ted Bates, 97 F.T.C. 230 (1981).

<sup>349.</sup> Standard Brands, 97 F.T.C. at 243; Ted Bates, 97 F.T.C. at 231.

<sup>350.</sup> Albano Enterprises, Inc., 89 F.T.C. 523, 528 (1977); Porter and Dietsch, Inc., 90 F.T.C. 770, 885 (1977); Cooga-Mooga, Inc., 92 F.T.C. 310, 320 (1978), modified, 98 F.T.C. 814, 816 (1981); Energy Efficient Sys., Inc., 97 F.T.C. 265, 286 (1981); Boekamp, Inc., 97 F.T.C. 291, 315 (1981); General Motors Corp., 104 F.T.C. 511, 512, 515 (1984) (all consent except *Porter & Dietsch*) (GM's agency, Campbell-Ewald also a named party).

The terms "endorsement" and "testimonial" appear to be used interchangeably by the F.T.C.

<sup>351.</sup> American Consumer Inc., 94 F.T.C. 648, 661 (1979); Leroy Gordon Cooper, Jr., 94 F.T.C. 674, 696 (1979); RR Int'l, 94 F.T.C. 1312, 1334 (1979); C.I. Energy Dev., Inc., 94 F.T.C. 1337, 1359 (1979); *Porter & Dietsch*, 90 F.T.C. at 886; Macmillan, Inc., 96 F.T.C. 208, 326 (1980); Great North Am. Indus., Inc., 98 F.T.C. 817, 831 (1981); Cliffdale Ass'n, Inc., 103 F.T.C. 110, 200 (1984).

touted a gasoline saving device. However, a single endorser is not likely to create the impression that multiple endorsers would create: namely, that the opinions of a wider group have been surveyed.

### E. General Misrepresentation Provisions

These are order provisions of a catch-all or boilerplate sort that cover violations generally, specifying no particular type of test or survey misrepresentation. Most of the orders discussed in this article contain such a provision, with wording such as this section: "It is further ordered, that respondent . . . do forthwith cease and desist from . . . [m]isrepresenting in any manner, directly or by implication, the purpose, content, sample, reliability, results or conclusions of any survey or test."<sup>352</sup>

There is virtually no discussion of these provisions. They always accompany other provisions pertaining more directly to the specifics of the case. Apparently the FTC wishes to curtail not only the actual practices but also those of a related sort that the advertiser might contemplate in the future.

Chrysler succeeded in having such a provision deleted on appeal because the court found it to "lack a reasonable relationship to the violations" and to be "potentially limitless."<sup>353</sup> However, when Litton cited that action<sup>354</sup> the Commission kept the provision.<sup>355</sup> In affirming the Commission's decision, the appellate court stated that "This prohibition, although broader than the facts of this case, is a reasonable 'fencing in' provision."<sup>356</sup>

### F. Records Maintenance Requirements

Most of the cases cited in this article include provisions for respondents to maintain documents relating to compliance. The following provision is a recent example:

IT IS FURTHER ORDERED that respondent . . . shall maintain written records:

1. Of all materials relied upon in making any claim or representation covered by this order;

2. Of all test reports, studies, surveys or demonstrations in its possession that materially contradict, qualify, or call into question the basis upon which respondent relied at the time of the initial dissemination and each continuing

<sup>352.</sup> Amana Refrigeration Inc., 102 F.T.C. 1262, 1266 (1983) (consent).

<sup>353.</sup> Chrysler v. F.T.C., 561 F.2d at 364.

<sup>354.</sup> Litton, 97 F.T.C. at 75 n.10.

<sup>355.</sup> Litton, 100 F.T.C. at 458.

<sup>356.</sup> Litton v. F.T.C., 676 F.2d at 373.

or successive dissemination of any claim or representation covered by this order.

Such records shall be retained by respondent for a period of three years from the date respondent's advertisements, sales materials, promotional materials or post purchase materials making such claim or representation were last disseminated. Such records shall be made available to the Commission staff for inspection upon reasonable notice.<sup>357</sup>

There is no discussion of these provisions. There is no indication that failure to maintain records constitutes a violation per se; rather, advertisers subject to other order provisions are made subject to this as well.

## G. Agency Defense Provisions

Advertising agencies, when prosecuted along with their clients, often are assessed less responsibility on the assumption that they are less well equipped to know whether a claim is substantiated. Ted Bates received the following addition to its order: ". . . [p]rovided, however, [t]hat it shall be a defense hereunder that respondent neither knew or had reason to know that the product, article or substance used in the test, experiment, or demonstration was a mock-up or prop."<sup>358</sup> The opinion added that "the agency will necessarily know of the use of mock-ups in commercials which it itself prepares."<sup>359</sup> Recent provisions have wording such as the following: "unless the respondent can establish it neither knew, nor had reason to know, nor upon reasonable inquiry could have known that such was the case."<sup>360</sup>

Batten, Barton, Durstine & Osborn argued on appeal that such a defense should have been applied in the instant case.<sup>361</sup> The appel-

In Standard Oil, the advertising agency BBD&O also benefited by being permitted to support its claims with tests "by it or its client," whereas its client was required to have its own tests. Standard Oil, 84 F.T.C. at 1490-91. Campbell-Ewald received a similar advantage in comparison to General Motors. See supra note 112 regarding different treatment of the two. The same analysis applies to STP and its advertising agency, Stern, Walters & Simmons. Id. at 66.

<sup>357.</sup> Associated Mills, 106 F.T.C. 5, 24 (1985) (consent).

<sup>358.</sup> Colgate Palmolive Co., 62 F.T.C. 1269, 1283 (1963) (consent) (Ted Bates also a named party).

<sup>359.</sup> Id. at 1278.

<sup>360.</sup> Standard Oil of California, 84 F.T.C. 1401, 1492 (1974) (BBD&O) also a named party). For similar provisions, see also: General Motors Corp., 104 F.T.C. 511, 515 (1984) (Campbell-Ewald also a named party); Dancer-Fitzgerald-Sample Inc., 96 F.T.C. 1, 14 (1980); Block Drug Co., 92 F.T.C. 852, 853 (1978) (two provisions) (Grey Advertising also a named party); STP Corp., 87 F.T.C. 56, 66 (1976) Stern, Walters & Simmons also a named party); Whirlpool Corp., 83 F.T.C. 1830, 1837 (1974) (DDB also a named party); American Home Prods. Corp., 81 F.T.C. 579, 586 (1972) (Cunningham & Walsh also a named party); Campbell Soup Co., 77 F.T.C. 664, 677 (1970) (BBD&O also named as a party); See also a similar provision in Allied Stores, 86 F.T.C. 1074, 1078 (1975). Although respondent was a retailer, the principle was the same in assuming a lesser responsibility for a peripheral participant.

<sup>361.</sup> Standard Oil of Cal. v. F.T.C., 577 F.2d 653, 660 (1978).

late court responded:

The advertising agency argues vigorously that it was entitled to rely on the elaborate safeguards, including independent laboratory tests and procedures for high level review, that preceded this advertising campaign .... Nevertheless ... [n]o specialized engineer was needed to put B B D & O on notice that a gauge which drops from a reading of 100 ("dirty") to 20 ("clean") implies a sweeping representation with reference to the change in level of pollution discharge. In light of the advertising agency's active participation in developing this advertising, it was BBD&O's responsibility to assure itself not only that the gauge was not rigged, but also that use of the gauge did not convey a dission's findings that, given the degree of participation by this advertising agency, it knew or should have known ....<sup>362</sup>

In *Thompson*, the advertising agency was offered an affirmative defense if:

prior to disseminating an advertisement containing the statement or representation challenged in such compliance action, JWT submitted to its client in writing all the performance claims which it reasonably believed were contained in the advertising prepared by it and exercised due care to assure itself that the advertiser possessed and relied upon a reasonable basis for those claims.<sup>363</sup>

In another case, Thompson, ordered not to make certain claims without a clinical test, was told the following:

where the clinical test or other evidence was not directly or indirectly conducted or controlled by JWT, it shall be an affirmative defense . . . for JWT to prove that it reasonably relied on the expert judgment of its client or of an independent third party in concluding that it had a reasonable basis . . . . Such expert judgment shall be in writing signed by a person qualified by education or experience to render the opinion. Such opinion shall describe the contents of such test or other evidence upon which the opinion is based.<sup>364</sup>

With respect to the use of surveys in the same case, the Commission stated the following:

in circumstances where the survey or sample was conducted by an independent third party and was not, directly or indirectly conducted or controlled by JWT or its client, it shall be an affirmative defense to an alleged violation . . . for JWT to prove that it had a reasonable basis for believing that the survey or sample was conducted in accordance with the provisions of . . . this Order.<sup>365</sup>

<sup>362.</sup> Id.

<sup>363.</sup> J. Walter Thompson Co., 94 F.T.C. 331, 338 (1979). Similar language was contained in Ted Bates & Co., 97 F.T.C. 220, 231 (1981).

<sup>364.</sup> Thompson, 97 F.T.C. at 336 (1981) (consent) (agency for Teledyne). The fact situations and provisions for several agencies were similar. See Ogilvy & Mather Int'l, Inc., 101 F.T.C. 1, 15 (1983) (consent) (agency for Thompson Medical), Stihl, Inc., 101 F.T.C. 840, 851 (1983) (consent) (Stuart Ford as agency); Foote, Cone & Belding Advertising, Inc., 102 F.T.C. 1274, 1283 (1983) (consent); Young & Rubicam/Zemp., 105 F.T.C. 317, 340 (1985).

<sup>365.</sup> Thompson, 97 F.T.C. at 335. Extensive description of the nature of a reasonable basis followed.

Clyne's client, American Home Products, was ordered not to make certain claims unless their truth was established through clinical tests.<sup>366</sup> In contrast, Clyne was ordered not to make those claims unless it "knows or has reason to believe that the [claim] has been established according to the terms set forth" in the order against AHP.<sup>367</sup> Clyne protested that "an advertising agency has no responsibility to conduct an independent examination of the relevant scientific evidence before participating in the creation of its clients' advertising programs."<sup>368</sup> The FTC, however, decided that "Clyne could not have reasonably relied on the AHP study."<sup>369</sup> The Commission denied that such a finding burdens agencies with a duty to conduct independent investigations. Rather, there was another alternative available to Clyne:

Clyne could easily have fulfilled its responsibility here by insisting that its client provide further substantiation or by disclosing the lack of proof or existence of a substantial question. We hold only that when presented with a facially inadequate study as substantiation, an advertising agency may not ignore the study's defects  $\dots$  370

A test, however, even though inadequate, might not be facially so. When Bristol-Myers received an order provision regarding the need for a reasonable basis, its agency, Ted Bates, received no comparable order, based on the following rationale:

what may not be a reasonable basis for a medical-scientific claim for a drug manufacturer may be a reasonable basis for an advertising agency which relied in good faith on the client drug manufacturer's judgment regarding the adequacy of substantiation unless the purported substantiation was unreliable on its face. . . . [Thus] We find that the substantiation for the tension relief claim did constitute a reasonable basis for Bates (although not for Bristol-Myers).<sup>371</sup>

Several agencies cited in this article were not granted an affirmative defense.<sup>372</sup> As elsewhere, coverage is restricted only to those cases involving tests or surveys.

<sup>366.</sup> American Home Prods., 101 F.T.C. at 699.

<sup>367.</sup> Id. at 702. See also DKG, 98 F.T.C. at 22.

<sup>368.</sup> American Home Prods., 98 F.T.C. at 397.

<sup>369.</sup> Id. at 398.

<sup>370.</sup> Id.

<sup>371.</sup> Bristol-Myers Co., 102 F.T.C. 21, 367 (1983).

<sup>372.</sup> Sterling Drug, 101 F.T.C. 375 (1983) (SSC&B also named a party); McCaffrey & McCall, Inc., 101 F.T.C. 367 (1983) (consent); Benton & Bowles, 97 F.T.C. 167 (1981) (consent); Porter & Dietsch, 90 F.T.C. 770 (1977) (Kelly Ketting Furth also a named party); Sorga, Inc., 97 F.T.C. 205 (1981) (consent); Perma-Strate Co., 87 F.T.C. 155 (1976) (consent) (Merrill Kremer also a named party); Admarketing, 94 F.T.C. 664 (1979) (consent); Parker Advertising, 87 F.T.C. 68 (1976) (consent); J. Walter Thompson Co., 84 F.T.C. 736 (1974) (consent); Sun Oil, 84 F.T.C. 247 (1974) (William Esty also a named party); Esty, the advertising agent for Sun Oil, was told it "clearly knew or should have known that [the] representations were false." Sun Oil, 84 F.T.C. at 274.

## H. Test Requirements Apart From Substantiation

Tests cited in this article typically are required only if the advertiser makes certain claims. In two cases, however, respondents were required unqualifiedly to make tests.<sup>373</sup> Two others were ordered to collect and retain product samples and be prepared to conduct tests at the FTC's option.<sup>374</sup>

### I. Contradictory or Inconsistent Claims

The complaint against ITT charged that it had "certain surveys of consumer attitudes conducted on its behalf . . . [and that] on the basis of these survey findings . . . knew or had reason to know or should have known that certain of the aforesaid advertisements constituted, and now constitute, 'false advertisements.' " $^{375}$  Therefore, the Commission ordered ITT to do the following:

cease and desist from ... disseminating ... any advertisement ... which represents ... any characteristic, property, quality, use or result of use of any such product which respondents know or have reason to know or should know by means of any marketing surveys, marketing reports, commercial attitudinal tests, commercial recall tests, or any other tests or surveys creates a misleading impression upon consumers or potential consumers of any such product.<sup>376</sup>

In *General Electric*, the complaint alleged that GE had represented that evidence obtained in 1973 regarding lower service levels of GE television sets (as opposed to other brands) was a reason to purchase such sets in 1974-75, although it had available subsequently acquired evidence which contradicted or was inconsistent with the survey evidence it relied upon.<sup>377</sup> Therefore, it was given this order:

cease and desist from advertising ... by reference to evidence ... when such evidence is inconsistent with or contradicted by any valid, reliable, or substantially identical evidence known to respondent unless at the time such representation is made: (1) respondent relies on an affidavit by a person qualified by training or experience to evaluate such evidence who, relying on standards generally recognized by qualified experts in that particular field, concludes that the inconsistent or contradictory evidence may be disregarded; and (2) the affidavit states the qualifications of the affiant and sets forth the generally recognized standards on which he relied in reaching his conclusion.<sup>378</sup>

Sears had advertised that its dishwashers required no pre-scraping

375. ITT Continental Baking Co., Inc., 79 F.T.C. 248, 251 (1971) (consent).

<sup>373.</sup> Montgomery Ward & Co., Inc., 95 F.T.C. 265, 276 (1980) (consent); Kettle Moraine Elec., Inc., 95 F.T.C. 398, 401 (1980) (consent).

<sup>374.</sup> Sovereign Chemical & Petroleum Products, Inc., 104 F.T.C. 478, 482 (1984) (consent); Pittsburgh Penn Oil, No. D-9203 F.T.C. slip op. (1986).

<sup>376.</sup> Id. at 254.

<sup>377.</sup> General Elec. Co., 89 F.T.C. 209, 214-15 (1977) (consent).

<sup>378.</sup> Id. at 217-18.

or pre-rinsing.<sup>379</sup> That claim was contradicted by instructions in the Owners Manual which told users they must pre-soak or firmly scour cooked or baked-on foods. Sears protested that its Owners Manual was mistaken. However, this testimony was deemed unreliable and self-serving.<sup>380</sup> In addition, Sears' dishwasher tests and marketing research gave contradictory evidence.<sup>381</sup>

Several additional cases included provisions directed to contradictory or inconsistent evidence.<sup>382</sup> Also, many cases require maintenance of records revealing contradictory evidence even absent specific charges that respondent had access to such evidence.<sup>383</sup>

This topic is similar to the Substantial Question cases.<sup>384</sup> However, it differs in that it involves evidence establishing the opposite of what was claimed, rather than showing that no conclusion is established. Nonetheless, the Substantial Question cases did raise questions of contradictory or inconsistent claims. A respondent might publish separate advertisements for two or more brands in the same product category, each making claims of superiority that must be mutually contradictory or inconsistent as a group.<sup>385</sup> As Commissioner Pertschuk protested, "[p]urely as a matter of logic, only one of these advertisers can possibly be telling the truth."<sup>386</sup> This theory of inconsistency failed in *Bristol-Myers* and *Sterling Drug.*<sup>387</sup> The *Sterling* decision called the idea a new theory contrary to existing understandings about substantiation.<sup>388</sup>

382. Sperry Corp., 98 F.T.C. 4, 9 (1981) (consent); DKG Advertising, Inc., 98 F.T.C. 15, 23 (1981) (consent); Heatcool, Inc., 101 F.T.C. 24, 32 (1983); Plaskolite, Inc., 101 F.T.C. 344, 350 (1983) (consent); Cynex Mfg. Corp., 104 F.T.C. 464, 475 (1984).

383. See note 357 and accompanying text.

384. See supra text accompanying notes 48-63.

385. This charge was made explicitly only against Sterling Drug, regarding claims for Bayer, Cope, and Vanquish brands. Sterling Drug, Inc., 102 F.T.C. 395, 402, 404-05 (1983). However, Bristol-Myers was charged with claiming Excedrin to be superior to any other nonprescription internal analgesic. Bristol-Myers Co., 102 F.T.C. 21, 30 (1983). In addition, American Home Products was charged with representing Anacin to be the same. *American Home Prods.*, 98 F.T.C. at 141. This prompted Commissioner Pertschuk to think in terms of the mutual contradictoriness in the entire "trilogy of analgesics cases." *Bristol-Myers*, 102 F.T.C. at 386.

386. Bristol-Myers, 102 F.T.C. at 386. See also Commissioner Pertschuk's concurring and dissenting opinions in Sterling Drug, 102 F.T.C. at 800.

387. Bristol's Excedrin claim was found not to have been made. *Bristol-Myers*, 102 F.T.C. at 326. Similar claims for the three Sterling brands were found to have been made and to be mutually inconsistent. *Sterling Drug*, 102 F.T.C. at 695-96. However, that was not found to constitute a violation. *Sterling Drug*, 102 F.T.C. at 696, 788-91.

388. Bristol-Myers, 102 F.T.C. at 789.

<sup>379.</sup> Sears, Roebuck & Co., 95 F.T.C. 406, 525 (1980), *aff* 'd, Sears, Roebuck & Co. v. F.T.C., 676 F.2d 385 (9th Cir. 1982). Other cases with similar provisions include the following: J. Walter Thompson Co., 94 F.T.C. 331, 338 (1979); Norris Indus., Inc., 92 F.T.C. 989, 1016 (1978); Energy Efficient Systems, 97 F.T.C. 265, 287 (1981); Boekamp, 97 F.T.C. 291, 316 (1981).

<sup>380.</sup> Sears, 95 F.T.C. at 514.

<sup>381.</sup> See discussion supra note 305.

# J. Misuse of Name or Authorization of Government or Testing Organization

A number of consent orders have forbidden misrepresentations of authorizations or approvals related to testing by government organizations.<sup>389</sup> Two respondents misrepresented the status of their own organizations.<sup>390</sup> National Dynamics was ordered to:

cease and desist from  $\ldots$  representing  $\ldots$  contrary to fact, that any product has been approved by any laboratory or by any other organization or person  $\ldots$ 

cease and desist from representing in any advertisement that an independent laboratory has tested any product or that any laboratory test substantiates or supports performance claims in said advertisement, unless each performance claim in said advertisement has been substantiated by a competent scientific test conducted by said laboratory or laboratories and unless such laboratory or laboratories have supplied respondents with a written report which describes, in detail, the entire test performed.<sup>391</sup>

On appeal, National Dynamics argued inconsistency with FTC's findings that the claims were substantiated. The court, however, ruled that the decision had not found that, but had found that the test reports (not the tests) constituted a reasonable basis for a respondent that lacked the expertise to know otherwise.<sup>392</sup> Thus, the respondent was not found lacking a reasonable basis for its product claims, but rather lacking a reasonable basis for its claim that those claims had been adequately tested by an independent organization.

390. Biochemic Research Found., 83 F.T.C. 1096, 1103 (1973) (consent) (the word "research" in the organization's name misled the public because they were not, in fact, a research organization); Scuba Diving Schools, 100 F.T.C. 439, 446 (1982) (consent).

391. National Dynamics Corp., 82 F.T.C. 488, 568-69 (1973), modified, National Dynamics v. F.T.C., 492 F.2d 1333 (2d Cir. 1974) (modifications not affecting tests), cert. denied, 419 U.S. 993 (1974), modified, 85 F.T.C. 391 (1975), modified, 85 F.T.C. 1052 (1975). Other cases in this category include the following: Revco D.S., Inc., 67 F.T.C. 1158, 1267 (1965); Nationwide, 74 F.T.C. at 83; Excel Chemical Corp., 74 F.T.C. 880, 885 (1968); Royal Indus, Inc., 83 F.T.C. 507, 512 (1973) (consent); Rapperswill Corp., 89 F.T.C. 71, 74 (1977) (consent); Teledyne, Inc., 97 F.T.C. 320, 331 (1981) (consent); Bristol-Myers Co., 102 F.T.C. 21, 392, 393 (1983); Amana Refrigeration Inc., 102 F.T.C. 1274, 1282 (1983) (consent); Foote, Cone, & Belding Advertising, Inc., 104 F.T.C. 845, 850 (1984) (consent).

392. National Dynamics, 492 F.2d at 1336. This is why the case isnot cited in the discussion of the RB/S Misrepresentation, supra at section VI.

<sup>389.</sup> Croton Watch Co., Inc., 59 F.T.C. 424, 427 (1961) (consent); Nationwide Indus., Inc., 74 F.T.C. 78, 83-84 (1968) (consent); Ex-Cell-O Corp., 82 F.T.C. 36, 44 (1973) (consent); Boise Tire Co., 83 F.T.C. 21, 25 (1973) (consent); Wasem's, Inc., 84 F.T.C. 209, 213-14 (1974) (consent); Robertson Prods., 87 F.T.C. 255, 264 (1976) (consent); Albano Enterprises, Inc., 89 F.T.C. 523, 527 (1977) (consent); Emergency Devices, Inc., 102 F.T.C. 1713, 1718 (1983) (consent); Monte Proulx, 102 F.T.C. 1722, 1726-27 (1983) (consent); Pharmtech Research, Inc., 103 F.T.C. 448, 459 (1984) (consent).

### K. Failure to Forward Evidence

The complaint against General Electric alleged a failure to keep an advertised promise to send consumers true and complete details about surveys of television buyers that provided comparative brand information. The company was told to cease:

[r]epresenting... that the details of any evidence will be forwarded upon request, unless respondent furnishes a fair and accurate summary of all the details of such evidence as to all products to which such representation extends, including the methodology used and any qualifications respecting the applicability of the results.<sup>393</sup>

### L. Requirements to Disclose Test Limitations

Provisions in two consent cases pertained to test limitations that should be disclosed:

cease and desist from: . . . [m]aking any statement or representation . . . respecting the moisture removal capabilities of dehumidifiers which is not based on tests conforming in all respects to the testing standards and procedures generally accepted and used by industry members, without clearly and conspicuously setting forth in immediate connection therewith the following statement: "Not rated by uniform industry testing methods. If industry tests were used, this dehumidifer would remove — pints less water per day or a daily total of — pints."394

cease and desist from: . . . [m]aking any representation . . . including through the use of testimonials, regarding . . . any live tests performed on the quartz tubes or resistance coils, without disclosing in close conjunction therewith, in print at least as large as the print in which the representation is made, or in an oral presentation, that the quartz tubes are: (1) fragile unless the quartz tubes are supported or protected in such a manner that they will not break when the Boekamp Heater is tipped over, and (2) not covered by the warranty or guarantee unless the quartz tubes are covered under the warranty or guarantee.  $^{395}$ 

## XII. CONCLUSION

The events discussed in this article have amounted to far more than the routine prosecution of deceptive advertising. They have constituted a two-decade period of substantial development of the law applied to claims regarding tests and surveys. As the era opened in the 1960's, blatantly false test demonstrations were the objects of prosecution, and virtually nothing regarding the nature of professional standards had been established. By the 1980's the prosecutions had advanced to reach the more subtle nature of the current misrepresentations. In addition, expectations regarding professional standards had been upgraded to extremely advanced levels.

Professionalization of standards arguably is the most significant

<sup>393.</sup> General Elec. Co., 89 F.T.C. 209, 218 (1977) (consent).

<sup>394.</sup> Berns Air King Corp., 76 F.T.C. 319, 323 (1969) (consent).

<sup>395.</sup> Energy Efficient Sys., Inc., 97 F.T.C. 265, 287 (1981); Boekamp, Inc., 97 F.T.C. 291, 314-16 (1981) (both consent).

impact of the cases discussed here. Since the early 1970's the FTC has hired numerous marketing and advertising researchers, from industry and universities, to serve as expert witnesses and/or full time staff employees to aid in its prosecutions. This author has served in both roles. The standards of such professionals, when applied to the research offered as evidence in the cases discussed here, have created a devastating indictment of the respondent advertisers. A student attempting to obtain a graduate research degree at typical United States universities, such as those attended by and/or staffed by the cited professionals, would be failed without mercy if caught applying the standards of these respondents.

The extent of inadequacy is often so extreme it seems unlikely to reflect mere inadvertence or neglect. The persons assigned to conduct research at the respondent organizations typically are so trained that they must have known the practices discussed were illegitimate. The picture presented, therefore, by reasonable hypothesis, is of a community that operated at a level of its own conscious choice. This author's best speculation as to why it happened is that respondents' perceptions of regulators' expectations were that it would suffice simply to be able to claim under threat of prosecution that some research had been done—any research! It must have been presumed that the findings would be accepted without scrutiny of the underlying methodology, which, when in fact scrutinized, so often stripped those findings of any validity.

The events described here may serve to indict the FTC as well, for the woeful level of its oversight at the era's beginning. The Commission was criticized on many grounds in the late 1960's for inept handling of its duties.<sup>396</sup> On the other hand, it may be that there were so few advertising references to tests and surveys before the 1970's that there were no vehicles available by which the Commission could have addressed these topics sooner than it did.

In any event, the cases seen here constitute an immense development in which the standards for advertisers' research, and claims based on that research, have been raised toward professional levels. The jeopardy advertisers now face for such misrepresentation constitutes the principal message of the order provisions examined in this article.<sup>397</sup>

<sup>396.</sup> Cox, Fellmuth, and Schulz, Nader's Raiders: Report on the Federal Trade Commission (1969); Report of the American Bar Association Commission to Study the Federal Trade Commission (1969).

<sup>397.</sup> Just prior to publication a proposed consent settlement was announced which

orders the first corrective advertising referring to tests or surveys (and indeed, the first corrective advertising since Warner-Lambert Co., 86 F.T.C. 1398 (1975)). In each ad during the next year respondent must disclose prominently that "Our earlier studies . . . do not meet the criteria of modern testing and therefore we no longer claim that the use of wheat germ oil or octacosanol will improve endurance, stamina or vigor, or any aspect of athletic fitness or performance." Viobin, 51 Fed. Reg. 36408 (Oct. 10, 1986). Also, at least one such ad must be run in each print publication in which Viobin Wheat Germ Oil was advertised during 1985. *Id*.