Appendix One: Building a Record on Advertising Meaning and Substantiation

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

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

A. Advertising Meaning

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

1. Express Claims

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

2. Implied Claims

Implied claims are not explicitly stated in the advertisement and range from those that use language and imagery "virtually synonymous with an express claim, through language that literally says one thing but strongly suggests another, to language which relatively few consumers would interpret as

making a particular representation."[4] Depending upon the nature of the implied claim, there are a number of means by which a record establishes the communication of an implied claim: (1) an analysis of the totality of the language and depictions of the ad itself, commonly referred to as a "facial analysis;" (2) extrinsic evidence in the form of marketing materials, general survey data or consumer survey evidence known as "copy tests;" and (3) extrinsic evidence provided by expert witnesses regarding what message or claim reasonable consumers are likely to take away from the ad.[5] These methods of proof have been used and upheld both in FTC administrative cases and in federal district court cases.

a. Facial analysis

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

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

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

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

b. Copy Testing

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

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

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

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

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

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

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

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

c. Expert Opinion

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

B. Falsity or Lack of Substantiation

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

asserting that the claim is true.[19] In practice, determining whether a claim is false or is unsubstantiated often requires the assistance of outside experts, as described below.

1. Expert Testimony

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

2. Proving A Claim Is Unsubstantiated

The first step in building a substantiation case is to obtain all of the advertiser's substantiation for that claim.[20] The expert must then evaluate the relevance[21] and scientific reliability of that material. The latter often involves an expert assessment of the adequacy of the design and conduct of a human clinical study,[22] of applicability of animal or *in vitro* studies to performance in humans,[23] the appropriateness or accuracy of statistical analyses,[24] and the consistency or fit of the proffered substantiation with the existing body of the relevant, well-conducted scientific research.[25] Following this assessment, the expert forms an opinion regarding the adequacy of the advertiser's proffered substantiation.

Advertisers may retain their own expert witnesses to undertake a similar analysis. Not

surprisingly, they often come to the opposite conclusion from the Commission's expert. Thus, the question of whether the advertiser's substantiation was adequate often becomes a question of fact as to the relevance and adequacy of the particular studies in the record. The Commission strives to use only the most qualified independent experts and to conduct a comprehensive review of all relevant substantiation.[26]

C. Materiality

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

The Commission presumes that express claims, intentionally made implied claims, and claims significantly involving health, safety, or other areas with which reasonable consumers would be concerned (e.g., claims pertaining to the product's central characteristics, purpose efficacy, or cost) are material.[28] However, an advertiser may rebut this presumption by offering evidence that a claim made was not in fact important to consumers. If the advertiser rebuts the presumption of materiality, the Commission will consider all of the evidence in the record in determining whether the claim was material. The evidence considered includes the predicate facts that triggered the presumption, for example, the fact that the advertiser was making a health claim.[29] The evidence considered also often includes internal company documents, such as survey evidence, marketing documents, and sales records.[30]

D. Conclusion

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

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1. *Novartis Corp.*, Dkt. No. 9279 (May 13, 1999), slip op. at 5, *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); *Kraft, Inc.*, 114 F.T.C. 40, 120 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993); *Thompson Med. Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); Letter to Hon. John Dingell, Chairman, Committee on Energy and Commerce, from James C. Miller, Chairman, Federal Trade Commission, 103 F.T.C. 174, 175-76, appended to *Cliffdale Assoc., Inc.*, ("Deception Statement").

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

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

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

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

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

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

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

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

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

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

12. *Thompson Med. Co.*, 104 F.T.C. at 793-94; *Novartis Corp.*, slip op. at 8-9.

13. *See Novartis Corp.*, slip op. at 9; *Kraft, Inc.*, 114 F.T.C. 127 n.13; S. Bonamici, *The Use and Reliability of Survey Evidence in Deceptive Advertising Cases*, 62 Or. L. Rev. 561, 584-85 (1983) (forced exposure method is more probative because it focuses directly on the message of the ad as opposed to "day-after-recall" tests which are designed primarily to measure how memorable the message is) (citing *Bristol-Myers*, 85 F.T.C. 688, 718 (1975)).

14. *See Novartis Corp.*, slip op. at 9; *Kraft, Inc.*, 114 F.T.C. at 127 n.13; *American Home Prods. Corp.*, 98 F.T.C. 136, 416 (1981), *aff'd*, 695 F.2d 681 (3d Cir. 1982).

15. Many consumer research providers also have trained, competent research designers who also can provide questionnaire design work as well.

16. *Thompson Med. Co.*, 104 F.T.C. at 790; *see Kraft, Inc.*, 114 F.T.C. at 121. However, Commission law makes clear that "[p]erfection is not the prevailing standard for whether a copy test may be given any [evidentiary] weight." *Stouffer Foods Corp.*, 118 F.T.C. at 807. Rather, the governing standard "is whether the evidence is reliable and probative." *Id.* A copy test may be flawed or include one or more sources of potential error or bias and still be probative. *Id.* Thus, the Commission or the courts will evaluate the nature and seriousness of any such errors or biases to determine the weight it will give to copy test evidence. *Id.*; *see Selchow & Righter Co. v. Decipher, Inc.*, 598 F. Supp. 1489, 1502-03 (E.D. Va. 1984). The marketing literature also contains a number of articles that summarize many copy test design-related issues. *See, e.g.*, Mazis, M.B., "Copy-Testing Issues In FTC Advertising Cases," Marketing and Public Policy Conference Proceedings, 122-30 (1996).

17. *See, e.g., Thompson Med. Co.*, 104 F.T.C. at 790 n.11.

18. *Id.* at 799; *Kraft, Inc.*, 114 F.T.C. at 126 n.13; *FTC v. Brown & Williamson Tobacco Corp.*, 580 F. Supp. 981, 986 n.31 (D.D.C. 1983), *aff'd*, 778 F.2d 35 (D.C. Cir. 1985).

19. *See, e.g., Thompson Med. Co.*, 104 F.T.C. at 818-19.

20. It is not uncommon for advertisers under investigation or even in litigation to submit new studies or data as they locate or create it. This material is referred to as "post-claim substantiation" and cannot be considered as substantiation that the advertiser possessed and relied upon at the time the claim was disseminated. However, the Commission will consider it with regard to interpreting the adequacy of the substantiating materials or to developing the scope of the order issued against an advertiser for violating the substantiation doctrine. Substantiation Statement, 104 F.T.C. at 841.

21. *See FTC v. Pharmtech Research, Inc.*, 576 F. Supp. 294, 302 (D.D.C. 1983) (reliance on studies of vegetables not relevant substantiation for claims for dietary supplement); *Schering Corp.*, 118 F.T.C. at 1093 (Initial Decision) (studies of weight loss product given in conjunction with restricted calorie diet not relevant to substantiating ad claims that product causes weight loss without a diet).

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

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

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

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

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

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

28. *See id.*

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

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

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