OPINION OF THE COMMISSION

By Anthony, Commissioner

This case is about a company that chose to market an over-the-counter ("OTC") analgesic by advertising that the product was superior to others in the treatment of back pain without any basis for that claim. Respondents Novartis Corporation and Novartis Consumer Health, Inc.[1] (collectively "Novartis") appeal from an Initial Decision and Order of Administrative Law Judge Lewis F. Parker (the "ALJ"), holding that superiority claims in advertisements for Doan's products were material and therefore deceptive in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45, 52. Complaint counsel cross-appeals the ALJ's decision not to order a corrective advertising remedy.

We affirm the ALJ's holding that the unsubstantiated superior efficacy claims for back pain relief were material and thus deceptive. We reverse the ALJ's holding regarding corrective advertising. We agree with the ALJ's findings and conclusions to the extent that they are consistent with those set forth in this opinion, and, except as noted herein, adopt them as our own.[2]

I. Factual Background

Novartis Corporation is a New York corporation and Novartis Consumer Health, Inc. is a Delaware corporation. Both are subsidiaries of Novartis AG, a Swiss corporation, and successors-in-interest to Ciba-Geigy Corporation and Ciba Self-Medication, Inc. (collectively "Ciba").[3] JX 2A ¶ 11.[4] In addition to the Doan's line, Novartis manufactures and sells other

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[1] Novartis is the successor in interest to Ciba-Geigy Corporation and Ciba Self-Medication, Inc. On April 23, 1997 the ALJ issued an order, pursuant to the agreement of the parties, substituting Novartis for Ciba as Respondent in this proceeding.

[2] We are in general agreement with the dissent regarding the applicable legal standards. The disagreements are over differing interpretations of the evidence.

[3] Ciba acquired the Doan's brand from DEP Corporation in early 1987. DEP Corporation had acquired the brand from Jeffrey Martin, Inc. shortly before. JX 2A ¶ 12. From January 1987 to December 1994, Ciba was responsible for the marketing and advertising of Doan's analgesic products. In December 1994, Ciba transferred the Doan's line of products to CSM, a wholly-owned subsidiary. CSM was responsible for the marketing and

(continued...)

OTC products.[5]

Doan's has been marketed and sold for over 90 years and has always been advertised as a backache product. IDF 8; Peabody Tr. 286. The active analgesic ingredient in the Doan's products is magnesium salicylate. IDF 14; JX 1 ¶ 11. While no other brand of OTC analgesic contains magnesium salicylate as an active ingredient, IDF 22; Peabody Tr. 314, there are no scientific studies demonstrating that magnesium salicylate is more efficacious than other analgesics. IDF 22; JX 1 ¶ 9. The Food and Drug Administration (the "FDA") regulates product labeling for Doan's pursuant to its *Tentative Final Monograph on Internal Analgesic, Antipyretic, Antirheumatic Products for Over-the-Counter Human Use* (the "Monograph"). Under the Monograph, an OTC analgesic drug may be labeled as indicated for the temporary relief of minor aches and pain associated with one or more of the following: cold, sore throat, headache, toothache, muscular aches, backaches, and arthritis. JX 1 ¶ 5.

Doan's is a relatively small player in a large market. In 1987, the total advertising spending for all OTC analgesic products was $299 million; for the first half of 1996 it was $351.1 million. JX 2D ¶ 23. Doan's advertising expenditures were a small fraction (1 to 3%) of the total analgesic advertising spending from 1988 to 1996. JX 2E ¶ 24. Between 1988 and 1994, Doan's share of the back pain advertising spending ranged from 8 to 12%. *Id*. Doan's analgesic products sell at a significant price premium over general purpose analgesic products at both the factory level (the retailer's purchase price) and the retail level (the consumer's purchase price). IDF 15.

After Ciba acquired the Doan's line in 1987, it commissioned a study, the Attitude and

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[3] (...continued)
advertising of Doan's analgesic products from December 1994 to March 1997. JX 2A ¶ 13.

[4] References to the record are abbreviated as follows:

IDF	Initial Decision Finding
ID	Initial Decision
Tr.	Transcript of Trial Testimony
CX	Complaint Counsel's Exhibit
RX	Respondents' Exhibit
JX	Joint Exhibit
RAB	Respondents' Appeal Brief
CCAB	Complaint Counsel's Answering and Cross-Appeal Brief
RRAB	Respondents' Reply and Answering Brief
CCRB	Complaint Counsel's Reply Brief

[5] These products include Ascription, Ciba Vision, Desenex, Dulcolax, ExLax, Gas-X, Habitrol, Maalox, Sunkist Vitamin C, Tavist-D, Theraflu, and Triaminic. IDF 5.

Usage Telephone Study (the "A&U Study"), CX 221, to find out how consumers perceived Doan's and to direct future marketing efforts. *See* Peabody Tr. 133-34. The A&U Study surveyed users of the Doan's product and non-users who were aware of the product. After analyzing the results of the A&U Study, Ciba's Marketing Research Department concluded that "Doan's has a weak image in comparison to the leading brands of analgesics and *would benefit from positioning itself as a more effective product* that is strong enough for the types of backaches sufferers usually get." CX 221-c,d (emphasis added). It further concluded that "Extra-Strength Tylenol is clearly the gold standard for backache pain relief followed by Advil. Bayer and Doan's are consistently perceived weakest." CX 221-c.

Ciba used the results from the A&U Study to create a new Doan's advertising strategy. Peabody Tr. 146. The strategy of this new campaign was to compare Doan's to other general analgesics. Comparative claims for small-share niche brands like Doan's are especially effective according to one of complaint counsel's experts, Dr. David Stewart. Stewart Tr. 3457. Specifically, Dr. Stewart explained that explicit comparative references made by low-share brands attract more attention to, and increased purchase intention for the low-share brand relative to the high share brand. Stewart Tr. 3458-59.

Ciba's marketing plans showed that its goals were to maintain its existing customers, to regain lapsed users and, of course, to attract new users. *See* CX 335-z-12; CX 343-z-65; CX 351-z-59. In the fourth quarter of 1987, Ciba introduced "Extra Strength Doan's," containing a larger dose of the active analgesic ingredient, and renamed the original product "Regular Strength Doan's." After its introduction, the Extra Strength product captured more than half of the Doan's product sales. JX 2B ¶18. In September 1991, Ciba introduced Doan's P.M., which contains a sleep aid.

Increasingly, Doan's faced competition from new back pain products, general analgesics, and private label brands. *See* CX 335-d; CX 343-f; CX 351-c; Peabody Tr. 146. The marketing plans outlined strategies to deal with such competition. For example, in August 1992, Ketchum Advertising prepared a "Doan's Defense Plan" intended to respond to the anticipated 1993 introduction of Nuprin Backache. *See* CX 357. The 1996 Marketing Plan reports that in 1994 Ciba regained its 1993 loss. CX 400-h.

To send its message, Ciba used national television ads and, to a lesser extent, free standing inserts ("FSIs"). Ciba disseminated FSIs in Sunday newspaper supplements two to three times per year. JX 2I ¶36. From 1987 through 1996, Ciba spent $55 million for broadcast ads and $10 million for FSIs. JX 2C ¶21. Doan's television ads appeared nationally both on network television and on syndicated and cable television. *See* JX 2F ¶28. The television ads were 15-second commercials. JX 2E ¶25. Ingrid Nagy, Doan's Business Unit Manager from 1988 to 1991 and its Marketing Director from 1994 to 1995, believed that 15-second ads were effective because of the fairly singular communication point of the ads. IDF 29; CX 499 at 135 [Nagy Dep.]. In addition, Ciba disseminated the television ads

through a flighting strategy[6] during 26 weeks of the year. Based on estimates by Ciba's advertising agencies, from 1988 to 1996, television commercials for Doan's reached 80% to 90% of the Doan's target audience, on average, between 20 and 27 times per year. JX 2F ¶28. Finally, for short periods in 1991 and 1993, Ciba tested radio ads including Spanish radio ads in Houston. JX 2I ¶¶34, 35.

II. Procedural Background

On June 21, 1996, the Federal Trade Commission (the "Commission") issued a complaint alleging that Ciba had violated Section 5 by making unsubstantiated claims in its advertisements (1) that Doan's analgesic products were more effective than other analgesics, including Bayer, Advil, Tylenol, Aleve, and Motrin, for relieving back pain; and (2) that Ciba possessed and relied upon a reasonable basis to substantiate such claims. During litigation, complaint counsel sought an order requiring that the following corrective notice appear on all advertising and packaging: "Although Doan's is an effective pain reliever, there is no evidence that Doan's is more effective than other pain relievers for back pain."[7] Complaint counsel sought to impose a performance standard for determining when the corrective notice was no longer needed. Specifically, the corrective notice would appear until Ciba (now Novartis) submitted consumer survey data to the Commission demonstrating that consumer beliefs had reached a specified level.[8]

After extensive discovery and an administrative trial, the ALJ issued his Initial Decision and Order on March 9, 1998. The ALJ found that a facial analysis of the challenged advertisements supports the conclusion that the advertisements conveyed a claim of superior efficacy for the treatment of back pain. The ALJ concluded that the Doan's superior efficacy claims were presumptively material because they relate to the central characteristics of the product and involve health claims. He also found that the claims cause consumers economic injury because the Doan's products are significantly more expensive than other OTC analgesics. He therefore held the superiority claims to be deceptive in violation of 15 U.S.C. §§ 45 and 52. Further, the ALJ concluded that Ciba intended to make the challenged claims. ID at 63-66.

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[6] In contrast to ads that are aired every week, flights are ads that air for several weeks and then are off the air for several weeks. Peabody Tr. 130.

[7] For TV, radio, or other broadcast advertisements, Novartis would have the option of substituting either of the following corrective notices: "There is no evidence that Doan's is more effective for back pain relief than other over-the-counter pain relievers;" or "There is no evidence that Doan's is more effective than other pain relievers for back pain."

[8] The performance standard was modeled after the 1996 NFO belief study relied upon by complaint counsel in this litigation.

The ALJ's order prohibits Novartis from making superiority claims for any OTC analgesic drug with regard to the product's ability to relieve back pain or any other particular kind of pain without competent and reliable scientific evidence that includes at least two adequate and well-controlled, double-blinded clinical studies. (Part I) As fencing-in relief, the ALJ's order prohibits Novartis from making any representation regarding any OTC analgesic drug's efficacy, safety, benefits, or performance without competent and reliable scientific evidence to substantiate the claim. (Part II) Finally, the order contains a "safe harbor" for claims approved by the FDA under a tentative or final monograph, or pursuant to an approved new drug application. (Part III).

The ALJ concluded that the record did not support the imposition of a corrective advertising remedy. He noted that a belief study, relied upon by complaint counsel, showed that a superior efficacy belief lingered for six months after the last challenged ad was disseminated. Nevertheless, the ALJ compared the 51 years Warner Lambert ran deceptive Listerine ads to the eight-year Doan's campaign and concluded that there was insufficient evidence that consumer misbeliefs in Doan's superiority for the treatment of back pain would linger in the absence of the remedy. ID at 64. Finally, he rejected complaint counsel's claim that the need for corrective advertising could be inferred.

III. Deception Analysis

A. Legal Standard

The first issue in this case is whether the challenged Doan's ads were deceptive. Section 5 of the Federal Trade Commission Act prohibits "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45. Section 12 of the Act declares dissemination of false advertisements regarding certain categories of products, including drugs, to constitute an unfair or deceptive act or practice under Section 5. 15 U.S.C. § 52.

As the Commission explained in its policy statement on deception, appended to *Cliffdale Assocs., Inc*. 103 F.T.C. 110, 176-184 (1984) (the "Deception Statement"), a representation is deceptive if it "is likely to mislead the consumer acting reasonably in the circumstances, to the consumer's detriment." *Id*. at 176. In practice, the Commission's deception analysis is applied as a three-part test asking whether (1) a claim was made; (2) the claim was likely to mislead a reasonable consumer; and (3) the claim was material. *E.g.*, *Cliffdale Assocs., Inc*. 103 F.T.C. at 165. There is no requirement of intent. *Kraft, Inc.*, 114 F.T.C. 40, 121 (1991) ("Evidence of intent to deceive is not required to find liability."), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993).

The factors and evidence the Commission weighs in assessing the three prongs of the deception analysis are often interrelated. While Novartis' sole question on appeal is whether the ALJ "err[ed] in concluding that the alleged implied superior efficacy claim was material to

consumers,'[9] RAB 7, its claims arguably implicate the other two parts of the test. Therefore, to address fully Novartis 'arguments on appeal, and to provide a context for our discussion of the materiality issue, we briefly discuss the first two elements before considering materiality.

B. The Challenged Ads Conveyed Superior Efficacy Claims.

We first consider whether the challenged ads communicated a superior efficacy claim for the treatment of back pain. In determining what claims may reasonably be ascribed to an ad, the Commission examines the entire ad and assesses the overall net impression it conveys. *Deception Statement*, 103 F.T.C. at 176; *Kraft, Inc.*, 114 F.T.C. at 122; *Thompson Med. Co.*, 104 F.T.C. 648, 790 (1984), *aff'd* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

Claims can either be express or implied. Here we are dealing with an implied claim. Implied claims range on a continuum. At one end are claims that are "virtually synonymous with an express claim" and use "language that literally says one thing but strongly suggests another." *Thompson Med. Co.*, 104 F.T.C. at 789. At the other end of the spectrum are claims that use "language that relatively few consumers would interpret as making a particular representation." *Id.*

The Commission's assessment of whether an implied claim is made necessarily begins with the advertisement itself. A facial analysis alone will suffice if it permits the Commission to conclude with confidence that the ad makes the implied claim. *See Stouffer Foods Corp.* 118 F.T.C. 746, 798 (1994); *Kraft, Inc.*, 114 F.T.C. at 121; *Thompson Med. Co.*, 104 F.T.C. at 789. In cases where the claim is not manifest from an examination of the ad, the Commission will look to extrinsic evidence. *Id.* at 799; *Kraft Inc.*, 114 F.T.C. at 121; *Thompson Med. Co.*, 104 F.T.C. at 789. Such evidence might include, for example, the testimony of expert witnesses, market research studies regarding consumer reactions to the use of certain common terms, or consumer surveys. *Kraft, Inc.*, 114 F.T.C. at 121-22. The Commission will carefully assess the quality and reliability of any extrinsic evidence introduced by the parties. *Stouffer*, 118 F.T.C. at 799; Deception Statement, 103 F.T.C. at 176. While methodological perfection is not required, with regard to reliance on copy tests and other consumer surveys, flaws in methodology may affect the weight the Commission gives to such results. *Id.*

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[9] In its appeal brief, Novartis states that while it "disputes the [ALJ's] finding that the challenged Doan's advertisements conveyed an implied superior efficacy claim to the requisite number of consumers under applicable precedent, it does not challenge that finding for purposes of this appeal." RAB 6. Novartis repeats that its appeal "challenges only the ALJ's conclusion that complaint counsel established the materiality of the alleged superiority claim," in its reply brief. RRAB 2. In a footnote, Novartis states that it is not conceding that the claim was communicated. *Id.* 2 n.1. By failing to appeal the issue, however, Novartis *has* conceded the issue for purposes of this litigation.

1. A Facial Analysis of the Ads Reveals That They Conveyed Superior Efficacy Claims.

Respondent ran the challenged ads over eight years.[10] JX 2E ¶25. The "Graph" ad was the first in the new campaign. It begins with a visual of the profile of a person in front of what appears to be graph paper. CX 13. The individual twice attempts to bend over; the second time (after he has implicitly ingested Doan's), he is able to bend farther. The audio portion of the ad states that "Doctors measure back pain by how far you can bend." The ad then depicts a package of Doan's on the left side of the screen while packages of three competing analgesic brands -- Advil, Tylenol and Bayer -- are displayed on the right. The audio portion concludes: "With an ingredient these pain relievers *don't* have." The spotlight on the other brands is then darkened leaving only a visual of the Doan's package on the screen.

The television ads Respondent disseminated after "Graph" continued to emphasize that Doan's has an ingredient not found in competing analgesics while depicting competing products. The "X-Ray" ad introduces an audio and visual reference to Doan's as "the back specialist," and this tag line is also used in several subsequent Doan's ads. CX 14. Respondent began to use the terms "special" and "unique" to modify references to Doan's "ingredient" in "Black and White Back" and "Ruin a Night's Sleep" ads, respectively. CX 15; CX 17.

The superiority themes begun in "Graph" and "X-Ray" continued in subsequent ads such as "Activity Playtime" and "Activity Pets." CX 20; CX 22. As in earlier ads, both depict a package of Doan's alongside other analgesics while the voice-over states, "Doan's has an ingredient these pain relievers don't have." And once again, the ads conclude with the "back specialist" tag line. Respondent repeated similar themes in the challenged "Muscles" ad. CX 23.

The Free Standing Inserts -- color print advertisements included with newspapers -- closely tracked the claims in the television ads. One FSI that first ran in 1989 and again in 1990 and 1991, features a large Doan's package alongside smaller but clearly visible packages of Advil, Extra-Strength Tylenol, and Bayer. CX 32. Copy above the packages states: "Doan's. Made for back pain relief. With an Ingredient these other pain relievers don't have." *Id*. Other FSIs made similar claims and included depictions of competing brands.

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[10] Graph (CX 13) ran from May 1988 through June 1991; X-Ray (CX 14) ran from August 1989 through June 1991; Black & White (CX 15) ran from June 1991 through October 1992; Black & White Pan (CX 16) ran from December 1992 through June 1994; Ruin A Night's Sleep (CX 17) ran from January 1992 through August 1992; Ruin A Night's Sleep (CX 18) ran from August 1993 through June 1994; Activity Playtime (CX 20) ran from July 1994 through July 1995; Activity Pets (CX 22) ran from July 1994 through July 1995; and Muscles (CX 23) ran from August 1995 through June 1996. JX 2E ¶ 25.

See., e.g., CX 33-39.

Based upon a facial analysis of the challenged ads, we find that they clearly conveyed a claim that Doan's is superior to other analgesics, such as Bayer, Advil, Tylenol, Aleve and Motrin, for relieving back pain. The express claims that Doan's is made for back pain and contains a unique or special ingredient that the other featured brands do not have, coupled with the depiction of the other brands, combine to communicate that Doan's is superior to the competing analgesics for back pain. This message is reinforced by the statement in some ads that Doan's is the "back specialist." The superior efficacy claim is implied, but on the continuum of implied claims, we find the claim so clear as to be nearly express.

2. Extrinsic Evidence Confirms That the Challenged Ads Conveyed Superior Efficacy Claims.

Substantial extrinsic evidence confirms our conclusion that the challenged ads make a superior efficacy claim. We affirm and adopt the ALJ's findings on this point (ID at 62-63), and highlight some of the more persuasive extrinsic evidence.

Several consumer surveys and copy tests show that consumers understood the ads to be making a superiority claim. For example, copy tests on mock-up versions of some of the challenged ads conducted by Bruno & Ridgeway, an independent consumer research company employed by Ciba, showed that approximately 30 to 45% of the consumers tested discerned a superiority message from the ads.[11] Likewise, a Mail Panel Communication Test conducted by Market Facts, a firm retained by Ciba to test the 1991 FSIs, revealed that between 47 to 59% of respondents strongly or somewhat agreed that the FSIs indicated that Doan's is better

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[11] Bruno & Ridgeway used a mall intercept methodology where qualified respondents were shown mock-ups of the ads and then asked questions. CX 224-d; Peabody Tr. 160. A mall intercept study is conducted in suburban shopping malls in different cities. Interviewers posted in the mall solicit passers-by to participate. Interviewers first determine whether a participant meets the demographic requirements of the study. If so, the participant is shown materials and asked questions. Peabody Tr. 358. Mall intercept studies are sometimes criticized as less demographically balanced than mail panel or telephone surveys because mall-goers are not necessarily representative of society at large. *See* Peabody Tr. 204. Tests of this nature are referred to as forced-exposure communication tests.

Thirty-eight percent of the consumers tested indicated that the "Graph" ad communicated, as a primary or secondary message, that Doan's was "superior to other products." CX 224-m. In response to open-ended questions, 44% of the consumers who saw the "Black and White" ad gave answers that were coded as "superiority over other products." CX 236-j. If responses to all of the open-ended questions are netted, 62% indicated that at least one ad conveyed a superiority claim. CX 236-m. Similarly, the results for "Ruin A Night's Sleep" ad reported that 23% of Doan's users and 38% of Doan's non-users gave answers that were coded "superiority over other products." CX 244-h,v.

for back pain than other pain relievers. CX 238-z-71. In addition, complaint counsel commissioned U.S. Research ("USR") to conduct a mall intercept copy test to determine if the challenged ads communicated the superiority claim. Fifty-seven percent of the "Activity-Playtime" ad and 40% of the FSI respondents took the superior efficacy claim from the ads. IDF 179, 180; ID at 63.

Ciba prepared these tests in the regular course of business, which indicates that at the time Ciba was running the ads, it was well aware that consumers understood them as conveying a superior efficacy message. Mr. Edward Peabody, the Director of Marketing Research, testified that he became concerned about miscommunication at the 10 to 15% level. Peabody Tr. 150-51. Nevertheless, as noted above, Ciba ran ads from which percentages of 30 to 45% drew a superiority message. While a respondent need not intend to make a claim in order to be held liable, evidence of intent to make a claim may support a finding that the claims were indeed made.

Novartis counters its own commissioned Bruno & Ridgeway test results with results obtained in ASI and ARS copy tests[12] that show low percentages of consumers drawing a superiority message from the ads.[13] We find that the ARS and ASI test methods likely understate the communication results. These were tests of recall and persuasion administered either one or three days after exposure to the ad. The legal issue in the first prong of deception, however, is whether the claim was made and not whether it was memorable. Forced-exposure tests, like those conducted by Bruno & Ridgeway, where questions are asked when the ad is fresh in the consumer's mind, are more telling regarding whether a particular claim was made. The ARS and ASI tests also tend toward understatement because their questionnaires contain no close-ended questions, and the open-ended questions asked consumers about express claims in the tested ads rather than what the ad implied or suggested. Peabody Tr. 194-95.

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[12] ASI tests expose consumers to commercials during pilot shows on unused cable channels. The consumer watches one or two pilots with test commercials embedded for Doan's and other products. Twenty-four hours later, consumers are called and asked questions about the ads. Peabody Tr. 181-83. ARS testing is similar to ASI testing except it is done in a theater-like setting, often at a hotel. Three days after seeing the pilot, consumers are called and asked questions about the ads. Peabody Tr. 350-52.

[13] Specifically, Novartis argues that a 1990 ASI copy test of "Black and White Back" reported that only 3% of the respondents questioned twenty-four hours after exposure to the ad reported that it communicated "product superiority," and that only 1% reported that it was "more effective/works better" in comparison to other products. Peabody Tr. 389; RX 98-h. Novartis also relies on ARS copy test data from 1991, 1993, 1994 and 1995 to show low percentages of consumer recall for a "more effective" or "good product/better/best" message within one to three days after exposure to the ads. RX 89-z-20; RX 32-y; RX 33-z-4; CX 265-z-2,3.

In sum, the issue of whether the claim was made is not a close one. While technically an implied claim, Respondent's superior efficacy message is plain from a facial analysis of the challenged ads alone. The extrinsic evidence introduced on this issue provides additional support for our finding that the superiority claims for back pain treatment were made.

C. The Challenged Ads Were Likely to Mislead Reasonable Consumers.

Having concluded that the claims were made, we proceed to consider whether those claims were likely to mislead reasonable consumers. Deception Statement, 103 F.T.C. at 177. The applicable standard is whether a claim is *likely* to mislead; proof that particular consumers were actually deceived is not required. *Kraft, Inc.*, 114 F.T.C. 133; *Cliffdale Assocs., Inc.*, 103 F.T.C. at 165; Deception Statement, 103 F.T.C. at 176. Further, "[t]he test is whether the consumer's interpretation or reaction is reasonable." *Id*. The interpretation need not be the only one to be reasonable. For example, a respondent can be held liable where multiple interpretations of a claim are possible, only one of which is deceptive. *Stouffer Foods Corp.*, 118 F.T.C. at 799; *Kraft, Inc.*, 114 F.T.C. at 120-21 n.8; *Thompson Med. Co.*, 104 F.T.C. at 789 n.7. The reasonableness of an interpretation is not contingent upon its being shared by a majority of consumers. A claim would likely mislead a reasonable consumer if at least "a significant minority of consumers" would be deceived by it. Deception Statement, 103 F.T.C. at 177 n.20. Importantly, the Deception Statement adds that an interpretation is presumed reasonable if it is one the respondents intended to convey. *Id*. at 178.

The misleading nature of the superior efficacy claims at issue here is plain. The claims are entirely unsubstantiated. Novartis concedes that no scientific studies demonstrate the therapeutic superiority of magnesium salicylate, the active ingredient in Doan's, over aspirin, acetaminophen, ibuprofen, or naproxen sodium for relief of back pain or any other indications contained in the Monograph issued by the FDA. JX 1D ¶ 9. As a general matter, the Commission considers claims regarding the efficacy of analgesics to be adequately substantiated when the claims are supported by the results of two well-controlled clinical studies. *Thompson Med. Co.*, 104 F.T.C. at 825. Here, the claim that Doan's is superior to various other OTC analgesics for treating back pain is baseless and, consequently, likely to mislead reasonable consumers.

This conclusion is bolstered by the fact that Ciba intended to make the superiority claim. Ciba knew from its own copy testing data that consumers were taking a superiority message from the ads and that it had no substantiation for such a claim. Indeed, more than a significant minority -- 30 to 45% -- of consumers discerned this superiority message. Yet, Ciba continued to run the ads. This demonstrates that Ciba intended to, and in fact did, convey a superiority message. Therefore, consumers receiving such a message from the ads behaved reasonably in doing so. *See Thompson Med. Co.*, 104 F.T.C. at 791.

Our finding of the reasonableness of the deceptive interpretation is further supported by

the nature of the product. Analgesics are products the efficacy of which consumers cannot readily judge for themselves. Well-documented phenomena such as the "placebo effect" and the "usage effect"[14] make it difficult for consumers to judge accurately the degree of an analgesic's efficacy. Superiority vis-a-vis other types of analgesics is even more difficult to ascertain absent well-controlled clinical trials. Thus, consumers necessarily rely upon manufacturers' representations and behave reasonably when they take those representations to be substantiated and accurate.

D. The Claims Are Material.

Finally, the Commission must determine whether the superior efficacy claim is material. A "material" misrepresentation is one that involves information important to consumers and that is therefore likely to affect the consumer's choice of, or conduct regarding, a product. Deception Statement, 103 F.T.C. at 182. Materiality is closely related to injury in that when a consumer's choice is affected by a misrepresentation, the consumer, as well as competition generally, is injured. *Id*. at 182-83. However, proof of actual consumer injury is not required. *Kraft, Inc.*, 114 F.T.C. at 134.

The ALJ concluded that the challenged claims were presumptively material, ID at 63-64, and found that the misleading claims were material based upon this presumption and the record evidence. IDF 227.

On appeal, Novartis argues that the ALJ misapplied the presumption, and improperly evaluated the evidence submitted by the parties. We conclude that the Respondent's implied superior efficacy claim was material.

1. The Presumption of Materiality

a. Generally

Novartis and *amicus curiae* Grocery Manufacturers Association argue that the ALJ improperly elevated the presumption of materiality to a virtually irrebuttable conclusion of law. We disagree.

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[14] The "placebo effect" is the tendency of patients to respond favorably to a treatment regardless of the treatment's medical efficacy. *See Thompson Med. Co*. 104 F.T.C. at 715 (Initial Decision.) The "usage effect" is the tendency of users of a product to rate it more highly than non-users of the product. Mazis Tr. 992, 1055-56. Users tend to use a product because they believe it works and thus tend to give it higher ratings than non-users. *Id* .; Jacoby Tr. 2987. This may be attributable, in part, to consumers' inability to evaluate effectively the efficacy of OTC analgesic products they use. *See American Home Prods. Corp.*, 98 F.T.C. at 282 (Initial Decision).

Certain categories of information are presumptively material, including, but not limited to, express claims, claims significantly involving health or safety, and claims pertaining to the central characteristic of the product. Deception Statement, 103 F.T.C. at 182. Similarly, the Commission will infer materiality where the record shows that Respondent intended to make an implied claim. *Id*. However, we "will always consider relevant and competent evidence to rebut presumptions of materiality." *Id*. at 182 n.47.

"To establish a 'presumption' is to say that a finding of the predicate fact," here, any of the factors listed above, "produces a required conclusion in the absence of explanation," here, materiality. *St. Mary's Honor Ctr. v. Hicks*, 509 U.S. 502, 506 (1993) (internal quotation marks omitted). In order to rebut the presumption, Respondent must come forward with sufficient evidence to support a finding that the claim at issue is not material. Respondent can present evidence that tends to disprove the predicate fact from which the presumption springs (*e.g.*, that the claim did *not* involve a health issue) or evidence directly contradicting the initial presumption of materiality. This is not a high hurdle. Unless the rebuttal evidence is so strong that the fact-finder could not reasonably find materiality, the fact finder next proceeds to weigh all of the evidence presented by the parties on the issue. *See id*. at 516 (noting that after the presumption drops out, "the inquiry . . . turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals . . . the parties have introduced"). While the presumption itself is negated by sufficient rebuttal evidence, as previously noted, the predicate facts that gave rise to the presumption are not. These facts remain evidence from which materiality can be inferred. *See Boise Cascade*, 113 F.T.C. at 975 (1990). However, this evidence is simply part of the entire body of evidence considered. *See also* 21 *Charles Alan Wright and Kenneth W. Graham, Jr., Federal Practice and Procedure: Evidence* §§ 5122 *et seq*. (1977 and 1998 Supp.) (discussing the history and application of presumptions).

b. The Facts Underlying the Presumption

The ALJ applied a presumption of materiality because the challenged claim involves a health issue. He also concluded that the presumption was appropriate in light of evidence that the challenged superior efficacy claim relates to the central characteristic of the product, that is, Doan's ability to relieve back pain. *See, e.g., Sterling Drug*, 102 F.T.C. at 753 (efficacy is "the most important feature of any analgesic"). Novartis admits that the presumption of materiality properly flows from these facts. RAB 46; RRAB 9.

We likewise conclude that these predicate facts -- that the claims go to health[15] and to a central characteristic of the product -- both support an initial presumption of materiality and constitute strong evidence that the claims were material. Common sense and experience, along with the Commission's expertise in advertising matters, counsel that Respondent's

[15] The record establishes that approximately 50% of adults in the United States suffer from back pain; thus, the treatment of that pain is an important health concern. CX 388-b.

representation that Doan's is more effective than other analgesics in the treatment of back pain was important to consumers considering a purchase and likely affected their decisions as to which product to buy. This requires no great leap.

Along with the "health claim" and "central characteristic" bases for the presumption of materiality, the ALJ found that Ciba's intent to make a superior efficacy claim was evidence that the claim was material and supplied an independent basis for the presumption. ID at 64. Novartis objects to this finding.

An advertiser's intent to make a claim generally implies that the advertiser believes that the claim is important to consumers. *See American Home Prods.*, 98 F.T.C. 136, 368 (1981) ("The very fact that AHP sought to distinguish its products from aspirin strongly implies that knowledge of the true ingredients of those products would be material to consumers."), *aff'd*, 695 F.2d 681 (3d Cir. 1982). Thus, the Deception Statement includes intent as a predicate fact giving rise to a presumption of materiality. 103 F.T.C. at 182; *see also Thompson Med. Co.*, 104 F.T.C. at 816. For express claims, the intent to make the representation is self-evident. In the context of implied claims, however, extrinsic evidence is required to establish an intent to make the claim.

Complaint counsel presents various documents showing that Ciba knew that the ads were conveying a superiority message. Novartis argues that the documents have been taken out of context and offers the testimony of employees who state that Ciba had no intent to make the claim. We find complaint counsel's evidence more credible and compelling and conclude that Ciba did indeed intend to communicate a superior efficacy message to consumers.

The record is replete with evidence demonstrating that Doan's ads were communicating a superiority claim and that Ciba management was aware of that communication. For example, the Bruno & Ridgeway communication study of the "Graph" ad categorized 38% of consumers exposed to the ad as answering that it communicated that Doan's was "superior to other products." CX 224-m. In a May 1988, memorandum to Ciba regarding the study, Bruno & Ridgeway recommended producing the ad, *inter alia*, because it "communicated *product superiority* and perceived efficacy." CX 225-d (emphasis added). This memorandum was directed to Ciba's Marketing Research Department and circulated to the Group Vice President of Marketing and other senior marketing executives at Ciba. In addition, the 1989 Doan's Marketing Plan prepared by Ciba reported the product superiority interpretation of the ad and described the "Graph" ad as a "strong execution which effectively communicates product superiority and perceived efficacy . . . ." CX 335-z-8.

Communication tests conducted for Ciba on its "Black & White Back," "Ruin A Night's Sleep," and "Activity Playtime" advertisements indicated that they communicated a product superiority claim as well. For example, the Bruno & Ridgeway copy test for "Black & White Back" reported that 46% of respondents recalled a message of superiority over other products. CX 236-j.

In May, 1994, Ciba's advertising agency, Jordan McGrath Case & Taylor, wrote to Ciba indicating that the networks were seeking substantiation for one of the implied superiority claims:

> *All three Networks are requiring substantiation for the claim "If nothing you take seems to help."* The Networks believe that this language implies that Doan's provides superior efficacy vis-a-vis the competitive products shown . . . . As such, to make this claim we will need substantiation that Doan's is more effective (due to its Magnesium Salicylate ingredient) at relieving back pain versus the competitors pictured.
>
> Importantly, our Agency coun[sel] agrees with the networks.

IDF 111; CX 165-a. In response, Ciba deleted the words "you take" from the ad copy so that the ad stated "if nothing seems to help." CX 20.

Despite its knowledge that the ads were communicating an unsubstantiated efficacy claim, Ciba continued to disseminate some of the ads until May, 1996, just a month before the Commission's decision to issue a complaint in this matter and well after its investigation had begun.

Novartis argues that Ciba did not intend to make a superior efficacy claim, but rather to distinguish Doan's from other products. Novartis primarily relies on the testimony of former and current Ciba/Novartis managers who stated that Ciba did not intend to make any superiority claims. We are unpersuaded by these *post facto* denials. They ring hollow in the face of the contemporaneous documentary evidence revealing knowledge that a superiority claim was being communicated. *See, e.g., United States v. E. I. du Pont de Nemours & Co.*, 353 U.S. 506, 602 (1957).

In sum, we agree with the ALJ that Ciba intended to make the superiority claim and conclude that this intent, along with the predicate facts that the claim goes to health and to a central characteristic of the product, create a presumption, and provide strong evidence, of materiality.

2. Complaint Counsel's Additional Evidence of Materiality

Along with the evidence that gave rise to the initial presumption of materiality, discussed above, the record contains substantial additional evidence supporting a finding that the claim was material. This diverse body of evidence includes consumer survey results, expert testimony, and business records.

a. The Nature of the Claims

The record contains ample evidence showing that superior efficacy claims are important to consumers attempting to choose a back pain remedy. First, experts for both parties testified that a superior efficacy claim would be important to the back pain sufferer when choosing an OTC analgesic. Mazis Tr. 1983 (testifying that superior efficacy is the primary reason why consumers choose one analgesic over another); Jacoby Tr. 3371 (testifying that superior efficacy claim would "motivate" back pain sufferers to purchase a product).

Second, the results of a study performed by Dr. Whitcup show the importance of efficacy claims. Dr. Whitcup asked consumers to rate the characteristics of pain relief products. Dr. Whitcup found that efficacy-related responses constituted three of the top four characteristics. RX 2-z-105. These results led Dr. Whitcup to conclude that analgesic products are generally chosen "on the basis of perceived efficacy," along with other factors. RX 2-z-3; Whitcup Tr. at 2815.

Third, several studies and copy tests Ciba commissioned in the ordinary course of business demonstrate the importance of efficacy claims to consumers of back-pain remedies. For example, a study delivered to Ciba management highlights a key finding: "[Doan's] is seen as particularly effective for back pain, and as having a special ingredient. . . . this specificity is what users are looking for . . . ." CX 256-c (Brand Equity Study, Exec. Summary). Similarly, Bruno & Ridgeway stated in its report on the copy test for the "Graph" ad that superiority "seems to be an important and persuasive idea." CX 224-l. Weiss Marketing Research Co. likewise concluded that the fact that the "Graph" ad created the impression that Doan's is better may persuade people to try Doan's. CX 227-z-3.

b. The Price Premium

Throughout the relevant period, Doan's was priced well above the general purpose analgesics depicted in the challenged ads, including Tylenol, Advil, and Bayer. In 1992, for example, a 24-count package of Doan's cost consumers 66% more than the same size package of Tylenol. IDF 15-16. The existence of this price premium constitutes further evidence of materiality. Deception Statement, 103 F.T.C. at 183.

Respondent argues that these price premiums cannot be linked to the challenged claim because the premium is attributable to Doan's status as a niche brand. RAB 83. However, the challenged ads compared Doan's to general purpose, lower-priced analgesics and not to other similarly priced niche products. Thus, the ads used a misrepresentation in an effort to convince consumers to pay the additional amount for a product similar to general purpose analgesics.

3. Novartis 'Evidence Against Materiality

Novartis offers several arguments to support its contention that the superior efficacy

claim was not material. While we find that Novartis submitted a sufficient amount of relevant evidence to rebut the presumption of materiality, the totality of the evidence strongly compels a finding of materiality.

a. Effectiveness of the Ads

Novartis primarily argues that the ads were ineffective in communicating their message to consumers and therefore did not affect consumer purchase decisions (*i.e.*, they were not material). Respondent argues that Ciba ran ads that it knew were ineffective in order to appease retailers who demand manufacturer support for niche brands.[16] RAB 56-57. Respondent cites market data for the relevant period that reflect little or no growth in sales or market share and reasons that the superior efficacy claim, therefore, did not affect consumer purchase behavior.[17] RAB 71.

In the first place, this claim is irrelevant even if it were true. Materiality is not a test of the effectiveness of the communication in reaching large numbers of consumers. It is a test of the likely effect of the claim on the conduct of a consumer who *has* been reached and deceived. *See* Deception Statement at 182-83. The materiality inquiry builds upon the findings from the prior two factors in the deception analysis -- that the claim was made and that it was likely to mislead at least a significant minority of reasonable consumers exposed to the ad. Materiality turns upon whether those consumers who have drawn the claim from the advertisement and been misled by it are also likely to have their conduct affected by the misrepresentation.

In any event, Respondent's argument that it ran an eight-year multimillion dollar campaign of ineffective ads is contradicted by the evidence. Market data demonstrate that the campaign produced positive results. Contrary to Novartis' assertions, Doan's maintained its market share in an extremely competitive environment and enjoyed an 80% increase in dollar

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[16] Novartis also argues that the evidence shows that consumers did not find the challenged ads interesting or persuasive. RAB 57-59. Even if this were the case, in the context of the materiality inquiry, it is the challenged claim that is at issue and not the ad as a whole.

[17] Along with its market *performance* arguments, Novartis advances a market *positioning* argument. Novartis contends that any superior efficacy belief that caused consumers to purchase the product was not the result of the misleading claim contained in the advertising, but rather was the result of product usage and Doan's historical market positioning as specifically for treating back pain. RAB 75-76. We reject this argument. The materiality inquiry focuses on the claim and its effect, not on other conceivable sources of consumer beliefs. Respondent's argument -- that if an advertiser is able to point to other possible sources for the misbelief engendered by its misrepresentation, it should be free to continue making its misrepresentation -- is untenable.

sales during the relevant period.[18] JX 2B ¶17. Because the number of consumers in the analgesics market in which Doan's competes is not growing appreciably (*i.e.*, the market is "mature"), a business must take customers from another brand in order to increase market share. Stewart Tr. 3467; CX 597. In such markets, maintenance of market share, and not increasing sales, is the primary criterion of success. *Id.* Indeed, Doan's ability to maintain its market share in the mature OTC analgesics market notwithstanding the fact that its advertising budget was much less than those of its competitors, JX 2E ¶24, reveals that the challenged advertising campaign was successful. The fallacy of Novartis' market performance arguments is also shown by Doan's survival and prosperity while other products were introduced and later withdrawn.

Even if Novartis' characterization of the market data were accurate, a history of static performance alone does not support its contention that the challenged ads were ineffective. Market performance is governed by a host of variables, and the materiality inquiry focuses upon a single claim.[19] Absent evidence, lacking here, that links market performance directly to the claim or controls for other variables influencing market performance, general market data is not particularly useful in assessing materiality.

b. Puffery

Novartis argues that the challenged claims were not material because they amounted to mere "puffing." RAB 61-64. Respondent posits that if consumers did not take the superiority claim seriously, the claim could not have misled them into buying the product. We reject this argument.[20]

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[18] Novartis argues that unit sales, and not dollar sales, is the more appropriate measure. Novartis contends that the strength of the dollar sales is misleading because it is attributable to the introduction of premium priced line extensions, namely Extra Strength Doan's and Doan's PM. These line extensions, however, were supported by the same advertising as regular Doan's and to the extent that the advertising was successful in convincing consumers to buy these premium-priced items, the profits made on these products suggest that the ads were having their desired effect.

[19] For example, the existence and strength of competitors, the availability of substitute products, the maturity of the market, the state of domestic and foreign economies, general business cycles, distribution issues, and trends in consumer preferences, among other factors, can all affect market performance and do not relate to an unsubstantiated superior efficacy claim made in an advertising campaign.

[20] In the first place, Respondent's puffing argument goes to ad interpretation, an issue properly considered in connection with the second prong of the deception analysis, rather than to materiality. *See* Deception Statement, 103 F.T.C. at 181 (puffing addressed as part of the

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The claim that Doan's is more effective than other analgesic products for treating back pain is not a subjective opinion, a matter of personal taste, or a hyperbolic statement that might be deemed "puffery." Rather, it is an objective claim that can be scientifically tested. The implied claim at issue here not only asserts superiority, but specifies in what respect (back pain relief), why (its unique ingredient) and compared to whom (named competitors). CCAB 93-94. This is the opposite of puffery, and the exact type of claim that a consumer would reasonably expect to be substantiated by adequate clinical studies. *See Pfizer*, 81 F.T.C. 23, 64 (1982) (puffing does not include "affirmative product claims for which either the Commission or the consumer would expect documentation").

Respondent also argues that approximately half of all consumers harbor a general belief that no analgesic is any more effective than any other in treating back pain. RAB 65-66. Presumably, Respondent's point is that these skeptics would never be swayed by false efficacy claims. Even assuming, for the sake of argument, the accuracy of the statistic and the validity of the claim that a consumer's general belief could not be overcome by specific misrepresentations, the argument still fails. An advertiser does not have to fool all of the people to be found liable; a "significant minority" of consumers is sufficient. Deception Statement, 103 F.T.C. at 177 n. 20. Nor does the existence of some hardened cynics free advertisers to make deceptive claims.

c. Consumer Surveys

Novartis offers various consumer survey results as support for its contention that the claim was not material. For the most part, the results touted by Respondent, even assuming flawless methodology, are only marginally probative on the issue of materiality. With respect to the one survey that tested materiality, methodological flaws render its results unreliable.

Respondent first points to the ARS tests, which indicate a low consumer recall of superiority messages between one and three days after seeing certain ads, as demonstrating that some of the challenged ads were not material. RAB 69-70. As discussed above, these tests asked only about express superiority claims, which were not made. Because the ARS tests did not even ask about implied claims (the only kind of claims at issue), they are hardly helpful. Moreover, materiality does not depend upon whether the claim is remembered by consumers days later. As discussed above, a claim does not have to be memorable to be material.

Novartis also claims that a study conducted by Dr. Jacob Jacoby in late 1996 shows that the superiority claim was not important to consumers and that the challenged ads were unlikely to cause consumers to purchase Doan's. RAB 76-79; RRAB 23-25. In Dr. Jacoby's

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[20] (...continued)
discussion of the reasonable consumer's interpretation of the claim). As noted above, Respondent has expressly waived any challenge to the second prong.

study, consumers were shown one of six commercials[21] and then questioned. Three of the questions (numbers 5a, 5b, and 5c) pertained to materiality. Question 5a asked: "Did seeing this commercial influence whether or not you would buy the advertised product in the future?" RX 5-z-112. Only those who responded affirmatively proceeded to question 5b: "Did it make you more likely to buy this product, or less likely to buy this product?" *Id*. Finally, those who responded "more likely," were asked 5c: "What is it about what the commercial said, showed or suggested that makes you more likely to buy it in the future?" RX 5-z-113. Dr. Jacoby contends that "only a trivial number" of those questioned indicated that the commercials made them more likely to buy the advertised product based upon a claim of superiority or because it had a special ingredient. RX 5-z-120.

Dr. Jacoby's test for materiality was flawed in several ways. First, by asking question 5c only of those who answered questions 5a and 5b in certain ways, Dr. Jacoby's study understated the number of respondents to whom the misrepresentation was material. Questions 5a and 5b ask about the *commercial* rather than the *claim*. Whether a commercial as a whole influences a consumer is not the same issue as whether a claim contained in the commercial is likely to do so. Despite the materiality of a given claim, the commercial containing that claim might fail to influence a consumer for any number of reasons. Because the claim need only be an important factor in the purchase decision, the results for questions 5a and 5b tell us little about the materiality of the superior efficacy claim.

Moreover, once the pool of respondents had been inappropriately filtered through questions 5a and 5b, their number had been drastically reduced. Of the 142 people shown the challenged "Activity Playtime" ad, only 35 were asked question 5c. RX 6-z-39. Similarly, of the 129 people shown the challenged "Muscles" ad, only 36 were asked question 5c. RX 6-z-15. These numbers appear to be too small to be accorded significant evidentiary weight.

Dr. Jacoby's study also understated the number of respondents to whom the superiority claims were material by failing to ask directly whether the superiority claim was important to them. The open-ended nature of question 5c tended to yield a scattershot range of responses. *E.g.*, RX 6-z-40. For each of the two challenged ads, seven of the approximately 35 people asked question 5c (roughly 20%) gave responses that Dr. Jacoby interpreted as indicating materiality. RX 6-z-16; RX 6-z-40. These results are almost certainly understated because Dr. Jacoby failed to ask follow-up questions to determine *all* of the aspects of the commercial that made consumers more likely to buy Doan's in the future. As previously noted, in order to be material, a claim does not have to be the *only* factor or the *most* important factor likely to affect a consumer's purchase decision, it simply has to be *an* important factor. By seeking only one response to question 5c for each consumer tested, Dr. Jacoby ignored this fact and thereby undermined his results.

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[21] Two of the six were challenged commercials, "Activity Playtime" and "Muscles." The remaining four were non-challenged controls. RX 5-z-101 n.1.

During the administrative trial, Dr. Jacoby sought to buttress his results by performing calculations cross-referencing several other questions included in the survey. While Dr. Jacoby did not explain his methodology in detail, he apparently matched the consumers he interpreted as drawing a superior efficacy claim from the ads (in response to questions 6a, 6b, and 8b)[22] with those who stated, in answer to question 5b, that the commercial made them "more likely" to buy the product. *See* RX 209-a. *See* Jacoby Tr. 3061, 3338-343. Based upon these calculations, Dr. Jacoby concluded that for the challenged commercials, the overlap was only 12.7 and 4.7%, respectively. *See* RX 209-a. He reduced these results further by subtracting the percentages obtained from the control ads. *Id*.

This procedure did not salvage Dr. Jacoby's study. The results of Dr. Jacoby's cross-referencing exercise derive from the results obtained from question 5b. That question only tells us which consumers found the commercial persuasive and does not reveal anything about what aspects of the commercial made it persuasive. As explained above, a claim by itself can be material and yet, when viewed in the context of a commercial, fail to persuade a consumer to buy the product. Therefore, question 5b improperly excluded many relevant respondents. As it is, Dr. Jacoby's results show that of the 35 consumers who indicated that they found "Activity Playtime" persuasive, 20 (57%) also drew a superior efficacy claim from the ad. *See* RX 209-a. While one might logically infer that the superior efficacy claim played an important role in making the ad persuasive to many of these consumers, the flaws in Dr. Jacoby's methodology preclude a definitive and quantified linkage.

Finally, Dr. Jacoby conceded that if a person suffers from back pain and is offered a product that is superior for the relief of back pain compared to other analgesics products, then that person would be motivated to purchase the product. Jacoby Tr. 3371. Thus, even Dr. Jacoby agrees that a superior efficacy claim is likely to affect consumers' purchase decisions.

E. Conclusion

Thus, although we have concluded that the evidence adduced by Novartis requires us to look beyond a simple presumption of materiality, our review of that evidence shows that it ultimately adds little to Respondent's side of the scales. Weighing *all* of the available evidence -- including the basic and irrefutable fact that the misleading claims of superiority relate to the central characteristic of the product and involve health; the evidence that the claims were

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[22] Question 6a asked the main idea of the commercial, and 6b asked about the other ideas the commercial was trying to get across. RX 5-z-96. Question 8a asked whether the commercial said, showed, or suggested that the advertised brand was more effective than other brands, and question 8b asked what the commercial said, showed or suggested that conveyed a superior efficacy claim. *Id.*; RX 5-z-139; RX 5-z-141. The results from these questions reveal a substantial communication rate for the challenged ads -- depending on the question, in the 30 to 50% range. RX 5-z-120-129; 139-148.

intended to affect consumer decisions; and the range of other evidence adduced by both sides -- we have no hesitation in concluding that the claims were material. The extensive record amassed in this proceeding strongly confirms the common-sense proposition that efficacy is a pivotal consideration for consumers in selecting an analgesic, and that claims of superior efficacy are highly material to those consumer choices.

IV. Corrective Advertising

A. Legal Framework For Imposing Corrective Advertising

Corrective advertising is an appropriate remedy if (1) the challenged ads have substantially created or reinforced a misbelief; and (2) the misbelief is likely to linger into the future. *See Warner-Lambert Co. v. F.T.C.*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978). In such cases, the lingering effects of a deceptive advertisement constitute a "clear and continuing injury to competition and to the consuming public" and justify the requirement of a corrective message. *Warner-Lambert Co.*, 86 F.T.C. 1387 (1975).

It is well settled that, in analyzing each of these two prongs, we may consider indirect evidence as well as direct evidence. *See, e.g., National Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *Warner-Lambert Co.*, 562 F.2d at 762; *American Home Prods.*, 98 F.T.C. at 407; Statement in Regard to Corrective Advertising, Trade Reg. Rep. (CCH) ¶ 39,046 (1979) (stating "that the absence of consumer research will not preclude a corrective advertising order if other factors in the evidentiary record indicate that the challenged advertising campaign has created or reinforced consumer beliefs"). Therefore, we reject Novartis' argument that reliance on inferences would be a departure from a "settled understanding" expressed in the corrective advertising case law. RRAB 53.

We also reject the ALJ's holding that corrective advertising is inappropriate absent "certainty" that the misbeliefs will otherwise linger. The proper standard is whether, by a preponderance of the evidence, the misbelief is *likely* to linger. A requirement of certainty that a misbelief will linger would be impossible to satisfy, because certainty about the future is unattainable.[23] The ALJ's finding that the false beliefs are not *certain* to linger applies the wrong legal standard.

Finally, we reject Respondent's argument that corrective advertising can only be ordered if it is shown that such a remedy is the *only* way to eliminate consumer

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[23] *Warner-Lambert* was a remarkable case. "Comparable proof of deception-perception-memory influence would be virtually impossible in most advertising cases. ... corrective advertising must apply to more than the one-in-a-million type of ad campaign present in *Warner-Lambert.*" R. Pitofsky, *Beyond Nader: Consumer Protection Regulation of Advertising.* 90 Harv. L. Rev. 661, 698 (1977) (footnote omitted).

misperceptions. RRAB 94 (citing *American Home Prods.*, 98 F.T.C. at 411). Contrary to the ALJ's suggestion, corrective advertising is not a drastic remedy. ID at 65. Requiring the dissemination of a truthful message to counteract beliefs created or reinforced by a respondent's deceptive message is an appropriate method of restoring the *status quo ante* and denying a respondent the ability to continue to profit from its deception.

B. Methodology of Belief Studies

To support a corrective advertising remedy, complaint counsel relies on three consumer belief studies to demonstrate (1) that the challenged advertising campaign created or reinforced misbeliefs harbored by consumers about Doan's, and (2) that those misbeliefs are likely to linger. Complaint counsel claims: First, that the A&U Study demonstrated that Doan's had a weak image compared to the other leading brands of general purpose analgesics in 1987, before the challenged ads were aired; second, that a Brand Equity Study, conducted mid-way through the campaign in 1993, showed that Doan's was then viewed as particularly effective for back pain and as having a special ingredient -- two claims that were the focus of the new campaign; and third, that a 1996 NFO study, commissioned by complaint counsel for this litigation, showed that users of Doan's and non-users who were aware of Doan's continued to harbor misbeliefs about the superiority of Doan's for back pain six months after the campaign had ended and that the misbeliefs were disproportionately high compared to the beliefs held for other products. One of complaint counsel's experts, Dr. Michael Mazis, also compared the results of these three studies, concluding that Doan's ads created or reinforced a superiority belief.

To counter complaint counsel, Novartis relies on three separate belief studies conducted for this litigation by Mr. Robert Lavidge, Dr. Morris Whitcup, and Dr. Jacob Jacoby. Novartis contends that these studies show that consumers do not have misbeliefs about Doan's. In addition, Novartis contends that the ARS and ASI copy tests and an Aleve Tracking Study, conducted by Ciba when Aleve was introduced into the OTC analgesic market, demonstrate low levels of unaided recall for the Doan's products. Novartis argues that if consumers are unaware of Doan's, they cannot harbor misbeliefs of any kind, and, thus, corrective advertising would be an inappropriate remedy.

The methodology and results of each of these studies are described in Appendix I.[24] The Brand Equity, Jacoby, and Lavidge studies used a mall intercept method. The A&U, Aleve Tracking, and Whitcup studies were conducted by telephone. Dr. Whitcup testified that telephone surveys are the most appropriate way of assessing consumer attitudes because their

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[24] As the Commission stated in *Stouffer* "[p]erfection is not the prevailing standard for determining whether a copy test may be given any weight. The appropriate standard is whether the evidence is reliable and probative." 118 F.T.C. at 807. While a given study may be flawed in some respects, it still can be probative, and any deficiencies simply will affect the weight given to the evidence. *Id.*

samples are most representative of the total population.[25] Whitcup Tr. 2107. Finally, the NFO study used a mail panel method. Mail panel research involves mailing research instruments to individuals who previously have agreed to serve as survey participants. These individuals complete and return the research instrument. The mail panels used by NFO were designed to achieve demographic balance.[26] Clarke Tr. 11. NFO panels are especially useful in identifying hard-to-reach consumers because of the large sample size. *Id*.

We initially discuss two criteria that affect the evidentiary value of the parties' consumer belief studies. First, consumer beliefs should be measured without exposing survey participants to the challenged ads. This is because such exposure may elicit the participant's interpretation of the ad rather than his or her beliefs. Second, the universe of participants surveyed should be properly selected to eliminate usage bias and to compare relevant groups. In testing for credence claims about a product, where consumers may have difficulty objectively evaluating the product's performance, the survey should insert controls to counter bias stemming from the use of the product.

1. Exposure to Advertising

All of the studies but one asked participants questions about their beliefs without exposing them to ads. Only the Lavidge study showed consumers television ads for four OTC products prior to questioning. Both complaint counsel's expert, Dr. Mazis, and Respondent's expert, Dr. Jacoby, testified that the appropriate way to measure beliefs is without exposure to ads. Mazis Tr. 1276; Jacoby Tr. 2962, 2968, 3155. By exposing consumers to advertising before asking questions about their beliefs, it is difficult to determine whether the consumers' responses to questions designed to elicit their beliefs reflect their interpretation of the ad or, in fact, their beliefs. We find that the Lavidge study is not probative of consumer beliefs because, contrary to the first criterion, participants were exposed to advertising as part of the study.[27] By contrast, the A&U, Brand Equity, NFO, and Whitcup, studies as well as the

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[25] Random digit dialing reaches both listed and unlisted numbers. Whitcup Tr. 2108.

[26] Mail panel participants may under-represent those with the lowest incomes (who may not have a permanent address or may be illiterate) and those with the highest incomes (who disproportionately decline to participate). Clarke Tr. 13.

[27] There are other flaws in the Lavidge study which may tend to understate the frequency of superior efficacy beliefs regarding Doan's. Dr. Mazis testified that it was difficult for consumers to answer the questions used in that study, because it required participants to sort through all the brands of which they were aware and then to make judgments about them. Mazis Tr. 1274-76. Moreover, Mr. Lavidge failed to control for usage bias; therefore, the fact that fewer of his participants used Doan's than used other products understated the superiority beliefs regarding Doan's. Mazis Tr. 1271. Mr. Lavidge even acknowledged that

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relevant portions of the Jacoby study were conducted in keeping with this criterion.

2. The Proper Universe

The appropriate universe is crucial to determine the probative value of any consumer survey. An improper universe can render a survey useless. Experts for both parties agreed that in a survey of consumers 'beliefs regarding Doan ŝ superior efficacy, the universe should be limited to those who suffer from and treat back pain. Mazis Tr. 1120; Lavidge Tr. 770; Whitcup Tr. 2109. All of the belief studies, with the exception of the Aleve Tracking Study, limited the universe of participants to those who suffered from back pain and had used an OTC analgesic product within the previous year. Because the Aleve Tracking Study was not confined to backache sufferers, the results are not particularly useful.[28]

The experts part company on the question of whether the survey respondents should be aware of the product for which the beliefs are tested. Complaint counsel ŝ expert, Dr. Mazis, concluded that the appropriate universe for testing consumer beliefs about Doan ŝ would include both people who were users of Doan ŝ and people who were aware of, but not users of, Doan ŝ (aware non-users). With such a universe it would be possible to compare the beliefs of users of Doan ŝ to users of other products. In order to control for usage bias, it is also necessary to compare the beliefs of people who were aware of the product, but not users, with the beliefs of users of the product. Mazis Tr. 1122-23. On the other hand, Novartis ' experts contend that a survey limited to participants who are aware of Doan ŝ would not be representative of the relevant population, and would tend to overstate ratings for Doan ŝ relative to other OTC analgesics. Whitcup Tr. 2182. In their belief studies, Novartis 'experts included consumers who were unaware of Doan ŝ. Dr. Jacoby testified that this was an important group of consumers because they were prospective consumers and they were the people to whom the advertising is directed. Jacoby Tr. 2937.

On balance, we conclude that the most reliable studies are those that focus on persons who have used Doan ŝ or are aware of the product. Because our inquiry is whether the Doan ŝ ad campaign has created or reinforced misimpressions about the product ŝ efficacy, it makes sense to direct our attention to those consumers who, in fact, have an opinion about

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[27] (...continued)
personal experience with a product is very important in shaping a consumer's beliefs about the product. Lavidge Tr. 750. The ALJ rejected the Lavidge study. IDF 310.

[28] Admittedly, the purpose of the Aleve Tracking Study was to track the introduction of Aleve on the OTC market generally, although it did develop some information about Doan ŝ. Dr. Mazis testified that the respondents in the Aleve Tracking Study were not focusing on back pain, so a back pain-specific product would be much less likely to be recalled. Mazis Tr. 2016.

Doan's -- which will necessarily be those who are aware of the product.[29]

The soundness of this approach is confirmed by consideration of the problem of user bias. Users of a product tend to rate it more highly than do non-users. Mazis Tr. 992.[30] This preference may be attributable, in part, to consumers' inability accurately to evaluate the efficacy of certain products -- such as analgesics -- relative to alternatives. *See American Home Prods. Corp.*, 98 F.T.C. at 282 (Initial Decision). Although the Whitcup and Jacoby consumer studies included consumers who were Doan's users (8% in Whitcup universe and 21% in Jacoby) the studies failed to ascertain the number of remaining consumers who were aware of Doan's, making it impossible to compare the beliefs of consumers who use the product to those who are aware of the product, but are not users. Accordingly, the most reliable assessments of consumer beliefs will be based on comparisons of like groups -- *e.g.*, users of one brand to users of another brand; or aware non-users of one brand to aware non-users of another. Only the NFO belief study used such a methodology. The NFO demonstrated that 77% of Doan's users and 45% of aware non-users believed that Doan's is superior to other brands.[31]

C. The Evidence Supports the Imposition of Corrective Advertising.

Having found that the superior efficacy claim was deceptive, and that a relevant universe of consumers believe that Doan's is superior, we must determine whether (1) the ads created or reinforced that misbelief; and, if so, whether (2) that misbelief is likely to linger. We address each of these issues in turn.

1. The Challenged Ads Created or Reinforced Misbeliefs.

A number of factors influence consumer beliefs about and attitudes toward a product, including advertising, use of the product, recommendations by doctors or others, and packaging. Mazis Tr. 1606-09; Lavidge Tr. 750-52. As a general matter, advertising and

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[29] Indeed, when Ciba itself tested consumer beliefs in the regular course of business, it limited its samples to those who were aware of the product. The A&U Study and the Brand Equity Study were confined to consumers who were aware of Doan's.

[30] *See* infra n..13.

[31] The Jacoby study, as far as it goes, actually corroborates the results of the NFO study. For example, in the Jacoby study, 38% of Doan's users reported Doan's as "more effective" in contrast to 23% of Advil and 17% of Tylenol users who reported their brands as "more effective." RX 5-z-105.

usage are among the most important of these factors.[32] *American Home Prods.*, 98 F.T.C. at 281. But product usage can be a primary source of a consumer's product image "only if the consumer has the ability to discriminate objectively between various similar products. . . . Thus, if a consumer is unable to evaluate objectively a product's actual efficacy, the role of advertising as a cause of the consumer image is enhanced." 98 F.T.C. at 410. Because consumers cannot objectively evaluate OTC analgesics, including Doan's, advertising is an important factor in creating and reinforcing beliefs about such products. Mazis Tr. 1609. The Doan's eight-year advertising campaign created and/or reinforced beliefs and made them more salient, understandable, and resistant to change. Mazis Tr. 1205-06. Indeed, such a long campaign could do both, having initially created and later reinforced beliefs.

After the 1987 A&U study showed that Doan's had a weak image, CX 221-c,d, Ciba launched the challenged advertising campaign, claiming that Doan's was superior to other general purpose analgesics for back pain and that Doan's contained a special ingredient for that purpose. Consumer survey data, conducted before final production of the ads, showed that consumers were drawing a superiority claim for back pain from the advertising. *See* ID at 62-63. The challenged superiority claims were consistent and made throughout the campaign. In fact, the eight-year campaign presented a focused message of comparative superiority.

The Brand Equity Study, conducted midway through the campaign, provides strong evidence that the advertising had already influenced consumer beliefs. Dr. Mazis' summary of that study shows that users of Doan's put Doan's in the top category for back pain efficacy twice as often as users of Tylenol, Advil and Motrin gave such a rating to the products they used. CX 480-a. Non-users who were aware of the product also rated Doan's more highly than the other brands (though less dramatically so). CX 480-c. Thus, in five years, the Doan's brand developed from having a weak image to being viewed by users and those aware of the brand as particularly effective for back pain.[33]

Moreover, changes in consumer beliefs during that five-year period closely tracked the claims made in the challenged advertising. Mazis Tr. 1057. Dr. Mazis' summary sets out the percentage of users and non-users who were aware of Doan's who believed two attributes

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[32] Indeed, word-of-mouth recommendations largely depend upon prior exposure to advertising and product usage. *American Home Prods.*, 98 F.T.C. at 281.

[33] Respondent argues, and the ALJ found, that the attribute of "being particularly effective for back pain" does not necessarily imply that a product is "more effective than other OTC pain relievers for back pain relief," and thus that the Brand Equity Study is not probative of superiority beliefs. IDF 246. We disagree. A product that is no more effective than any other would not be "particularly" effective. The word "particularly" is inherently comparative. *See, e.g., Webster's New International Dictionary* 1783 (2d ed. 1938) (defining "particularly" as "[e]specially; unusually").

claimed in the challenged ads (superiority for back pain and use of a special ingredient) and a third that was not advertised (superiority for all kinds of pain). CX 480-c. Consumers tended to perceive Doan's as particularly effective for back pain and also as containing a unique ingredient.[34] Mazis Tr. 1058. The non-advertised attribute (effectiveness for all kinds of pain), however, was not believed by many consumers. CX 480. Accordingly, the Brand Equity Study supports the conclusion that the challenged ads played a substantial role in creating or reinforcing consumer misbeliefs about Doan's.

The results of the NFO belief study similarly show that in 1996, a disproportionately high percentage of Doan's users and aware non-users believed that Doan's was more effective than other OTC pain relievers for back pain relief. CX 482. Dr. Mazis testified that the Doan's advertising played a significant role in creating or reinforcing the superiority belief. Mazis Tr. 1216-18.

Dr. Mazis also compared the results of the 1987 A&U Study with the 1996 NFO study. He testified that this analysis shows that "superior efficacy" beliefs for Doan's relative to Advil, Bayer, and Tylenol increased (between 0.5 and 1.25 scale points on a seven-point scale) between 1987 and 1996 relative to other brands, as did beliefs that Doan's has a "special ingredient" (between 0.75 and 1.875 points). At the same time, consumer beliefs that Doan's "is safe to use" -- a claim not made in its advertising campaign -- declined in rough proportion to the other products. CX 532-e, h, k; Mazis Tr. 1244-45. Dr. Mazis concluded that this striking pattern, in which changes in consumer beliefs mirrored advertising themes (or their absence), confirms that the ads created or reinforced the misbeliefs. Mazis Tr. 1246. The ALJ rejected Dr. Mazis' comparison of the studies because of the differences in their methodologies and questions asked. IDF 350. While we acknowledge the methodological differences between the studies, we believe that these data nonetheless corroborate the connection between the ads and the misbeliefs.[35] *See* IDF 351, 352.

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[34] Dr. Mazis testified that consumers would not infer that a product had a special ingredient for back pain simply from the fact it is only advertised and marketed for back pain. Mazis Tr. 1621.

[35] Contemporaneous documents further indicate that Ciba's ad agency, Jordan McGrath, recognized that the challenged advertising was affecting superiority beliefs about Doan's among consumers. One such document from 1994 stated that:

> [t]he 1993 Brand Equity study showed that the specificity of Doan's positioning, as communicated by "The Back Specialist" campaign line has helped differentiate the Brand from other pain relievers. Clearly this unique positioning has contributed to this.

CX 387-y. (Doan's FY '95 Marketing Plan Key Issues, July 25, 1994.)

(continued...)

We reject Respondent's contention that the Aleve Tracking Study and the Whitcup Study demonstrate a low unaided recall of Doan's advertising, so consumers cannot harbor misbeliefs about Doan's. RRAB 61, 62. We have already noted that because the Aleve Tracking Study was not confined to back pain-sufferers, its results are not useful. It tends to understate those consumers who may have beliefs about Doan's and did not ask back pain-specific questions. And the results of the Whitcup study are undermined by the small number of Doan's users sampled (35) in contrast to the number of Tylenol users (190) and Advil users (121). RX 2-z-49. Indeed, Dr. Whitcup himself appended the letter "c" (designating "caution" due to a small base) to data regarding Doan's user responses.

As in its attack on materiality, Respondent argues that the Whitcup, Lavidge, and Jacoby studies show that a majority of consumers do not believe that any OTC analgesic brand was more effective than others for relieving back pain, RRAB 63, 64, presumably rendering advertising ineffectual in creating or reinforcing any superior efficacy beliefs. Even if those studies show that a *majority* of consumers so believe, a *substantial number* of respondents remain who believe that one brand may be more effective than others. *See* RX 23-j; RX 2-t; RX 6-j. The results do not shed light on whether the challenged ads created or reinforced misbeliefs in the minds of these remaining consumers.

Novartis also recycles its argument that, even if consumers harbor misimpressions about Doan's, such beliefs are due to Doan's ninety-year positioning as a back-specific analgesic and not to the challenged ads. RRAB 75-77. In fact, however, there is no record evidence to support Respondent's speculation. To the contrary, the A&U Study showed that Doan's historical positioning did not have a major impact on consumer beliefs, and that the product's image remained weak prior to the commencement of the ad campaign at issue here. CX 221-c. As the evidence discussed above shows, the ensuing multi-million dollar, eight-year campaign was successful in enhancing the product's image by persuading consumers, incorrectly, of Doan's superior efficacy. In any event, even if that misimpression existed to some degree prior to the ad campaign, the campaign at the very least had the effect of *reinforcing* such beliefs, which to supports a corrective advertising remedy. *See Warner-Lambert Co.*, 562 F.2d at 762. In fact, the campaign could have both created and reinforced misbeliefs in that beliefs may have been created and later reinforced.

We likewise reject Respondent's argument that complaint counsel failed to establish a link between consumer beliefs and the challenged advertising. Respondent claims that the

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[35] (...continued)

Similarly, Jordan McGrath's Vice President Account Supervisor who worked on the Doan's account noted the effectiveness of the challenged claims: "'The Back Specialist' we have kind of engraved that in the consumer's mind." CX 503 at 97 [Jackson Dep]. Other Ciba documents indicate the significant role that advertising played in driving Doan's sales. CX 404-a-b; CX 499-a.

NFO study is flawed because Dr. Mazis did not ask survey participants whether they were aware of Doan's advertising. RRAB 79.[36] While a specific question asking whether participants recalled the challenged advertising might have been useful, we find that the failure to include such a question was not a fatal flaw. The evidence of parallel changes in consumers' beliefs about Doan's that track the course of the eight-year campaign sufficiently establishes the link between the challenged ads and the resultant misbeliefs.

Respondent further claims that the ads did not create or reinforce misbeliefs because the campaign was ineffective in communicating its superiority message (again repeating a claim employed to attack materiality). Novartis argues that Doan's used a small advertising budget and relied on "worn out" ads. *See* e.g., RAB 16, 23; RRAB 1. Such a campaign, it claims, would be incapable of creating misbeliefs in the minds of consumers that would justify corrective advertising. This line of argument, however, is not only inconsistent with the evidence already discussed regarding the campaign's actual effects but is also belied by Ciba's actions during the campaign, which evince its reliance on the campaign.

Ciba continually refined its marketing plans in response to changing demographic information. Ciba conducted research to define precisely the target audience of backache sufferers and revised its media plans accordingly. For example, after learning that its target audience was disproportionately female and Southern, the yearly marketing plans considered these factors in developing media strategies and ad placement. CX 335-z-14; CX 343-z-64. Ciba's decision to test Spanish radio ads in Houston during short periods in 1991 and 1993 is another example of Ciba's responsiveness to changing demographics. Similarly, when competitors entered the market, Doan's responded through defensive advertising. When Nuprin Backache was introduced in the first half of 1993, Ciba increased Doan's television advertising budget by approximately $500,000. CX 357-b. When Bayer Select Backache was introduced, Ciba increased its spending to run more advertising during the new product's introductory period. CX 378-k. A Marketing Director wrote that Doan's used "a consistent strong advertising campaign to defend and even build share in the face of these new competitors." CX 399-b.

Finally, Novartis' resort to market share data and statistics wholly fails to show that the ads could not have created or reinforced consumer misbeliefs. Respondent claims that Doan's unit sales actually declined during the relevant period; that even when measured against OTC analgesics used to treat backache, Doan's market share stood at 5%; that Doan's

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[36] Dr. Mazis testified that he did not ask whether people had seen advertising for Doan's because at the time of the NFO study, the ads had not run for six or seven months, and people might not reliably recall ads that they did, in fact, see. Mazis Tr. 1797. He also testified that beliefs from ads may linger even though recall of specific ad claims may not. Mazis Tr. 1798, 1800.

was unable to increase its sales and market share even after dropping its price,[37] and that any increases in factory or consumer dollar sales resulted from the introduction of the Extra Strength and PM lines. RAB 17-19. In fact, the sales volume fluctuated during these years rather than declining and Novartis 'expert, Dr. Scheffman, relied upon incomplete data that did not extend beyond 1993. RX 189-a. Volume sales increased by 10% in 1995. CX 402-c; CX 408-h. Further, Doan's share of the total analgesic category grew from 0.8 to 0.9% between 1993 and August 1995, a 12.5% increase, and there was nearly an 80% increase in factory sales. JX 2B ¶17. Moreover, in a mature market, a key criterion for advertising success is maintenance of market share. Stewart Tr. 3467. And, a variety of marketing plans during the relevant period indicate that sales were responding well to ads. CX 360-z-43; CX 393-q; CX 408-i. Accordingly, we conclude that the challenged ad campaign was successful, and that the challenged ads created or reinforced misbeliefs among consumers regarding the superior efficacy of Doan's.

2. The Effects of the Challenged Ads Are Likely to Linger.

We next turn to the question whether the misimpressions caused or reinforced by the challenged advertisements are likely to linger in the absence of corrective advertising.

The NFO study, conducted six months after the ads ceased, demonstrates that 77% of Doan's users and 45% of those who were aware of but did not use Doan's believed that the product was superior to other brands for the treatment of back pain. These percentages are disproportionately high for both groups relative to other brands.[38] Thus, the NFO study shows

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[37] Respondent also argues that the low share of usage, conversion rates, and advertising penetration data demonstrate that consumers do not believe that Doan's is more effective than other analgesics for the relief of back pain. RRAB 59-60. At best, these factors serve as an inexact proxy for consumer beliefs. The direct evidence shows that consumers believed that Doan's was superior to other OTC analgesic products.

[38] Respondent's arguments that the NFO study is flawed, RRAB 67-71, are without merit. As noted above, the NFO study used an appropriately restricted universe, and its protocol was proper and provided reliable results. Respondent argues that the absence of follow-up validation procedures renders the data unreliable. But all experts agreed that the purpose of validation is to deter and detect interviewer misconduct, Mazis Tr. 1128; Lavidge Tr. 788; Jacoby Tr. 2950-51. we therefore find that this mail panel study (which did not utilize an interviewer) did not require validation. Respondent's concern that the wrong household members may have completed the survey questionnaires, thereby rendering the results unreliable, is unwarranted. The study employed mechanisms to account for this possibility, Clark Tr. 40-41, and eliminated questionable responses.

Finally, Novartis questions the significance of the NFO study results. Dr. Mazis

(continued...)

that, for at least six months after the challenged ads stopped being aired, their effect continued to linger.

A Novartis expert, Dr. James Jaccard, re-analyzed the NFO data, attempting to measure the magnitude of the differences in brand attribute ratings, RX 132 f-o, and to demonstrate that there likely are not meaningful differences in brand efficacy beliefs held by those who use or are aware of Doan's and those who use or are aware of other OTC analgesics. Jaccard Tr. 1427. In fact, Dr. Jaccard's testimony does not undermine the conclusions of Dr. Mazis and the NFO study.

First, Dr. Jaccard has no expertise regarding the OTC analgesic market and does not know whether any of the differences in effectiveness beliefs in the NFO study were significant. Jaccard Tr. 1523. Second, he conceded that traditional null hypothesis testing, as used by Dr. Mazis, is the dominant analytic technique, Jaccard Tr. 1510, and that his own approach is not common. Jaccard Tr. 1444-45. Third, Dr. Jaccard acknowledged that the differences observed in the NFO study might be practically significant. Jaccard Tr. 1450-51.

A number of factors that support the results of the NFO study also support an inference that consumers' false beliefs are likely to endure. *See American Home Prods.*, 98 F.T.C. at 411. Specifically, the challenged claims were (1) very salient to consumers (because superior efficacy is among the primary considerations for a consumer in selecting a back pain remedy), (2) clearly and consistently conveyed by the challenged ads, and (3) an integral part of an eight-year campaign. Respondent spent approximately $65,000,000 disseminating these claims, primarily in fifteen-second ads whose primary message was the false superiority claim. The ads reached between 80 and 90% of Doan's target audience approximately 20 to 27 times each year. JX 2F ¶ 28. A likelihood of lingering effects can also be inferred from copy tests, which demonstrated that consumers drew a superiority claim from the Doan's ads after just one or two exposures.[39] *See Warner Lambert*, 86 F.T.C. at 1470.

Novartis' expert, Dr. Scheffman, testified that any misimpression created by the Doan's ads is not likely to linger due to Doan's insignificant advertising spending and the placement, length, and frequency of the challenged advertising compared to the amount of

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[38] (...continued)
analyzed the different sets of ratings for joint users of Doan's and one of the other five brands and found that, on average, 25% more people rated Doan's as superior for back pain relief. IDF 263. The comparative analysis for non-users who were aware of several products revealed that, on average, 20% more people rated Doan's superior. IDF 265. This demonstrates a strong difference in beliefs among these groups. Mazis Tr. 1196-1199.

[39] Dr. Mazis testified that the beliefs are likely to linger in light of the length and effectiveness of the ads, the fact that they stressed the superiority claim repeatedly, and the recall evidence from the copy tests. Mazis Tr. 1255-56.

advertising in the OTC analgesic marketplace. Scheffman Tr. 2612-13. We reject the argument that market share, total sales, or the relative size of the advertising budget determine whether a misbelief is likely to linger. All of these factors go primarily to the purported *magnitude* of the harm created by the deceptive ads and not to the likelihood that the misbelief will linger.[40] Moreover, niche marketers who engage in deceptive campaigns should not be immune from a corrective advertising requirement simply because of the relative size of their advertising budget or market shares.

Respondent also contrasts the evidence of lingering misbeliefs in *Warner-Lambert*, in which we ordered corrective advertising, to that in cases where we declined to order corrective advertising. RRAB 96. Novartis argues that we have rejected corrective advertising in three cases where challenged ads were disseminated for a longer period of time than those in this case, where the advertising budget for the challenged campaign was larger, and where there was higher consumer recall of the specific challenged claims. RRAB 47.

We disagree that such a comparison counsels against corrective advertising here. First, we have frequently noted that the amount of evidence in *Warner Lambert* was unusually strong and far exceeded the threshold needed to impose corrective advertising. "We emphasize that we do not believe corrective advertising may only be imposed where there is an evidentiary basis like that in *Warner-Lambert*." *American Home Prods.*, 98 F.T.C. at 408 n.93 (citations omitted.).[41] Second, none of the three cases relied upon by Respondent involved comparable evidence to support a corrective advertising remedy. In *Bristol-Myers Co.*, 102 F.T.C. 21 (1983), complaint counsel introduced "no evidence" that misbeliefs would likely linger. *Id.* at 380. We declined to infer a likelihood of lingering solely from the face of the challenged ads. *Id.* Similarly, in *American Home Products Corp.*, we refused to infer a likelihood of lingering merely from the nature of the ads notwithstanding a total absence of evidence on that issue in the record.[42] 98 F.T.C. at 409. In *Sterling Drug, Inc.*, 102 F.T.C. 395 (1983), we found that the misrepresentations had not created or reinforced misbeliefs in light of studies conducted both before and after the challenged campaign revealing the same

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[40] In any event, in a mature market, such as OTC analgesics, a central purpose of advertising is to retain current users and a key criterion for an ad campaign's success is whether it is succeeding in maintaining share, particularly in the face of a competitive onslaught. IDF 335; Stewart Tr. 3467. We find that Doan's was able to maintain and even increase its sales in light of the competitive pressures of new entrants in the back pain category and affirm the ALJ's finding on this point. IDF 336.

[41] *See, supra*, footnote 23.

[42] Some of the claims in that case were also secondary to the main message of the ads. 98 F.T.C. at 408.

levels of consumer misbeliefs.[43] *Id*. at 798. These cases are easily distinguished from this one, where extensive evidence supports each prong of the corrective advertisement test.[44]

Respondent next contends that low unaided brand awareness, evinced by consumer survey testing, demonstrates that the ads did not convince consumers that Doan's is more effective than other brands,[45] RAB 39-40, 73-75; RRAB 59, and thus no misbeliefs can linger. The advertising penetration data are not probative. Apart from the serious methodological flaws with the belief studies noted above,[46] this low brand awareness -- even assuming it exists -- is relevant only to the magnitude of the harm that Respondent's false ads caused, and not to the likelihood that such harm as was caused will linger.

The ALJ found that the ARS and ASI studies, revealing 2 to 8% recall of a "more effective" or a "good product/better/best" message after 24 and 72 hours, suggest that any misbelief may be transitory. ID at 64. We disagree. These were communication studies that asked what the ad said or showed, not what consumers believed about the product. The data from these tests thus do not establish the nonexistence of consumer misbeliefs. Consumers may hold beliefs about a product without recalling advertising that contributed to such beliefs. *See* Jacoby Tr. 3201. This is especially true with respect to a credence good, such as an OTC analgesic, for which consumers cannot easily evaluate the truth or falsity of claims. Moreover, the studies do not even purport to measure the duration of misbeliefs among those who were, in fact, misled, which is, after all, the relevant inquiry.

The record establishes that consumers held misbeliefs about Doan's superior efficacy,

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[43] Complaint Counsel in that case conceded that the frequency of misbeliefs was not altered by the challenged ad campaign, but argued that the misbeliefs "nonetheless became 'sharper'" as a result thereof. 102 F.T.C. at 799.

[44] The dissent's emphasis upon the duration of the advertising campaign and dollars spent in these cases neglects the absence in those cases of sufficient evidence demonstrating a likelihood of lingering misbeliefs. This analysis cannot be reduced to a rigid algorithmic inquiry.

[45] The Aleve Tracking Study indicates that Doan's had a 2 to 3% unaided brand awareness in December 1994 and June 1995, respectively. RX 101-t. None of the 423 respondents in the Whitcup belief study reported "top-of-mind" awareness of Doan's advertising. RX 2-o.

[46] For example, the Aleve Tracking Study focused on general analgesics and was not confined to backache sufferers; thus, it is not surprising that consumers did not mention Doan's, which is not marketed as a general analgesic. Moreover, Novartis' own expert, Dr. Jacoby, conceded that penetration studies are of questionable value in measuring consumer beliefs about a product. People can form and retain beliefs based upon an ad without recalling it. Jacoby Tr. 3201.

that such beliefs were created by or substantially reinforced by the challenged advertising campaign, and that those beliefs are likely to linger into the future. Therefore, we find that the elements for corrective advertising are satisfied, and that corrective advertising is appropriate and necessary.

Corrective advertising is appropriate for an additional reason. We previously discussed the factors which, separate from the NFO study, support an inference that misbeliefs about the superior claim are likely to linger. Another inference arises under these facts. We cannot turn a blind eye to the obvious relationship between an absolute efficacy claim ("this product works"), which Doan's has been running for ninety years, and a comparative efficacy claim ("this product works better than others"). Given that Novartis' advertising campaign fostered a symbiotic relationship between these two claims, simply to permit Novartis to return to its ninety-year old positioning of Doan's as a backache product makes it all the more likely the misbeliefs will linger -- absent some corrective action.

3. Content of the Corrective Message

Dr. Mazis testified that, as a general matter, proper corrective advertising accomplishes its intended effect of dissipating misbeliefs over time. IDF 358-59. Studies designed to track the impact of corrective advertising imposed in *RJR Foods, Inc.*, 83 F.T.C. 7 (1973) and *Warner Lambert* support this conclusion. IDF 360.

The corrective message should (1) state that Doan's products are effective; (2) correct the lingering misbelief that Doan's products are superior to other products; and (3) permit Respondent to continue to advertise Doan's specifically for back pain.[47] The following corrective message proposed by complaint counsel satisfies all of these requirements: "Although Doan's is an effective pain reliever, there is no evidence that Doan's is more effective than other pain relievers for back pain." We find that this slightly longer version of the corrective message is more balanced than the suggested alternatives for shorter television or radio ads. We recognize the FDA monograph allows pain specific advertising and do not want to impede Novartis' ability to make claims specifically allowed by FDA. For all these reasons, the corrective message in the present matter is inevitably somewhat complex.

Both parties conducted studies to test the effectiveness of this corrective message. Dr. Mazis tested the message in FSIs in a telephone survey involving 370 consumers.[48] Dr. Mazis concluded that the corrective message was effectively communicated with a very low level of

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[47] The FDA monograph allows pain-specific advertising, and Novartis is free to make claims specifically allowed by FDA.

[48] Of the respondents, 145 were Doan's users and 225 were non-users who were aware of Doan's. CX 489.

miscommunication of the unintended message that Doan's is less effective.[49] Dr. Jacoby criticized the study because he did not believe that a mail panel method was appropriate to test the corrective message as a general matter. He also criticized the use of FSIs to test the corrective message since FSIs were not a large part of the advertising campaign.

Dr. Whitcup conducted a study of the same corrective message using a mall intercept methodology with the corrective message placed on the product package. Dr. Whitcup concluded that the corrective message did not convey the intended message to consumers[50] -- of the 35% who saw the disclaimer, 10% got it wrong. Dr. Whitcup argued that number to be high given the small number who recalled the disclaimer at all. Accordingly, he concluded that the corrective message did not do a good job of communicating its message. Dr. Mazis criticized the Whitcup study, noting that the corrective message appeared in a cluttered context. He found that the message was inconspicuous and difficult to read. Mazis Tr. 1353-56.

We find that the Mazis study is probative of the effectiveness of the corrective message. We also find that the Whitcup package study actually confirms the effectiveness of the corrective message. We believe that the different levels of communication between the Whitcup product package study and the Mazis FSI study result from their differences in the conspicuousness of the disclosure and the fact that packages contain a great deal more information than advertising.

Although we have no data to determine at what level the message would be communicated in a 15-second television or radio ad, we believe that the corrective message would be difficult to communicate in such a short ad without unduly restricting Respondent's ability to also convey its advertising message. Accordingly, we require that the corrective

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[49] In response to the question, "What did the ad say or imply about Doan's?" 38% of the participants indicated that Doan's was the same as or was not proven to be better than other medicines. Only 3 to 4% indicated that it was better or worse. CX 489-p. In response to closed-ended questions regarding what the ad said or implied about Doan's effectiveness for back pain in comparison to other medicines, 69% replied that it was the same or not proven to be better. Between 5 and 8.8% reported that it was better or worse. CX 489-x. Finally, in response to closed-ended questions about what was implied or stated, 75% agreed that the ad implied that Doan's is about as effective for back pain as other OTC pain relievers. None said it was less effective and 17% said it was more effective. CX 489-z.

[50] In response to an opened-ended question asking what the package said, showed or implied about the product, 15% responded that they understood that Doan's was not more effective than other pain relievers. RX 110-q. In response to a closed-ended question as to whether the package compared effectiveness of the product to the effectiveness of other pain relievers, 35% said yes, but 6% said the product was better and 4% said it was worse and 24% said it was the same. RX 110-v.

message appear on all advertising except television and radio ads that are 15 seconds or less in duration. The corrective message must also appear on the product package. Including the corrective message on the product packaging is especially important because, as Dr. Whitcup testified, packaging is a particularly ubiquitous form of advertising in that people have to pick up the product in order to purchase it. Dr. Whitcup also noted that in deciding what product to buy, consumers may compare packages. *See* Whitcup Tr. 2286.

We reject complaint counsel's recommendation that the duration of the corrective message be determined by a performance standard. In *Egglands Best*, we required the corrective message to appear on the package for one year. 118 F.T.C. 340, 357. In *Warner Lambert*, we required the corrective message to appear in all advertising until the respondent had expended a sum equal to the average annual Listerine advertising budget for a ten-year period. 86 F.T.C. 1514-1515. The Court of Appeals affirmed, stating: "[T]he corrective advertising order in this case, by tying the quantity of correction required to the investment in deception, is tailored to serve the legitimate governmental interest in correcting public misimpressions as to the value of Listerine and no more." In a footnote, the court went on to say: "As a result, any imprecision in the order's scope would seem likely to inure to Warner-Lambert's benefit." 562 F.2d 771.

We believe that a hybrid approach -- advertising expenditures and specific length of time -- is the best method for determining when the corrective message should terminate. If we were to require that the corrective message appear in advertising until Novartis has expended a specific amount of money on advertising, Novartis could choose to advertise for a short period of time in an expensive way. If we were to require the corrective message to appear only for a specific period of time, then Novartis could choose not to advertise for that period of time.[51] Accordingly, we order that the corrective message appear for one year on all packaging and advertising, except radio and television ads of 15 seconds or less in duration, and until Novartis has expended on Doan's advertising an amount equal to the average spent annually during the eight years of the challenged campaign.[52] In contrast to complaint counsel's proposed performance standard, as the Court of Appeals found in the *Warner Lambert* matter, any imprecision in the scope of the order is likely to inure to Novartis' benefit.[53]

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[51] Indeed, an internal Novartis document suggests that if we order corrective advertising, they could stop advertising for three years. *See* CX 110-c.

[52] Respondents spent $65.3 million on advertising between 1988 and 1996. JX 2d ¶ 21. The average annual expenditure on advertising is $8 million.

[53] Dr. Mazis' expert testimony was that the belief that Doan's is more effective than other OTC pain relievers fro back pain will likely linger for a long time after the claim is no longer disseminated. Mazis Tr. 1255-56. Dr. Mazis' expert opinion is supported by three empirical (continued...)

Respondent argues that complaint counsel's proposed corrective advertising order violates the First Amendment. RRAB 106. Respondent argues that the corrective message does not convey the intended message and may be confusing. In addition, it argues that the corrective notice will be punitive because it will have a negative influence on consumers' beliefs about Doan's. RRAB 104. Further, it argues that the message would force it to abandon the 15-second ad format. RRAB 110. Finally, it argues that the corrective message "carries an unacceptable risk of forcing Doan's to abandon its back pain specific positioning and thus forcing Doan's off the market." RRAB 106. These arguments rely on Respondent's assumption that the corrective message could be perpetual because of the performance standard suggested by complaint counsel.

We reject these arguments. First, the corrective remedy is of a finite duration. Second, it will not force Respondent to abandon 15-second ads because it does not apply to such ads. Third, the corrective message was effectively communicated and is not unduly confusing or misleading. Finally, it is not punitive to require Respondent to tell the truth.

We now turn to the specific First Amendment arguments. Respondent asserts that complaint counsel's proposed corrective advertising provision would prevent it from truthful speech and require it to underwrite speech about the merits of other brands. RRAB 107-108. It relies on *Ibanez v Florida Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136 (1994). That case involved a reprimand by the Florida Board of Accountancy ("Board") of a Florida attorney for including her Certified Public Accountant and Certified Financial Planner credentials in her advertising and other communication to the public. *Id.* at 139-41. The United States Supreme Court noted that the challenged statements were true and that the government had nothing more than speculation or conjecture to support its fear that the listing of her credentials would, in fact, mislead consumers, by implying compliance with the relevant state accountancy regulations. *Id.* at 143, 144-47. In the present matter, we are not dealing with an across-the-board ban on truthful speech as was the case in *Ibanez*, but with commercial speech which was subject to an adjudicative proceeding and was found to be deceptive.

While commercial speech is entitled to First Amendment protection, misleading speech is not protected and may be banned entirely. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 477 U.S. 557 (1980). Nonmisleading commercial speech may be regulated if the regulation meets a three-prong test: (1) the government's interest in regulating the speech must be substantial; (2) the regulation must materially and directly advance these interests; and (3) the regulation must be no more extensive than is necessary.[54] *Id.* at 566.

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[53] (...continued)
studies that evaluated the effects of Commission corrective advertising orders. IDF 359.

[54] Although decided before *Central Hudson*, *Warner-Lambert* addressed the First (continued...)

We apply the *Central Hudson* test to the facts of this case. First, the government has a substantial interest in protecting consumers from deception. *See Warner Lambert*, 562 F.2d at 771. Thus, the first prong of the test is satisfied.

With respect to the second prong, we find that the corrective advertising remedy directly and materially advances the aforementioned governmental interest. We have determined that the challenged advertising has created or substantially reinforced misbeliefs in the minds of consumers and that those beliefs are likely to linger into the future. As discussed above, the corrective advertising remedy we order has been copy tested by both parties, and the results show that it effectively communicates the desired message. Accordingly, we conclude that the corrective advertising remedy advances the governmental interest in preventing future deception by correcting the lingering effects of Doan's past false advertising.

Finally, we conclude that the remedy is no more extensive than necessary. Our order is narrowly drafted to correct the misbelief at issue. We have balanced the need for correcting the lingering misbeliefs of consumers against Novartis' ability to advertise effectively. In doing so, we have been mindful of imposing less restrictive alternatives where appropriate. Therefore, we have specifically exempted television and radio ads whose duration is 15 seconds or less to achieve the proper balance. Accordingly, we find that the last prong of *Central Hudson* has been satisfied.

V. CONCLUSION

After a careful review of the entire record and after consideration of all the arguments made by the parties, we believe that Doan's advertising claims were material, the required elements of corrective advertising have been satisfied, and a corrective advertising remedy is appropriate.

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[54] (...continued)
Amendment issue and concluded that the First Amendment did not bar a corrective advertising order. 562 F.2d 768-71 (supplemental opinion on petition for rehearing).