IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 09-3909

FEDERAL TRADE COMMISSION, Plaintiff-Appellant,

v.

LANE LABS-USA, INC.; I. WILLIAM LANE; and ANDREW J. LANE, Defendants-Appellants,

and

CARTILAGE CONSULTANTS, INC., Defendant.

On Appeal from the United States District Court for the District of New Jersey No. 2:00-cv-03174

BRIEF OF PLAINTIFF-APPELLANT FEDERAL TRADE COMMISSION

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STATEMENT REGARDING ORAL ARGUMENT

Appellant respectfully requests oral argument as to all issues.

STATEMENT OF JURISDICTION

The Federal Trade Commission ("FTC" or "Commission") initiated the underlying action in the United States District Court for the District of New Jersey seeking relief for defendants' violations of Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45. The district court's jurisdiction over this matter derives from 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 53(b).

In this appeal, the Commission seeks review of an order entered by the district court on August 11, 2009, denying the Commission's motion to hold defendants in contempt for violations of the Stipulated Final Orders for Permanent Injunction ("Final Orders") entered in this case. That order is final and reviewable under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES PRESENTED

1. Whether the district court abused its discretion in ruling that the Commission failed to show by clear and convincing evidence that defendants violated the Final Orders entered in this case, where the court misconstrued the Final Orders and ignored the ample undisputed evidence presented by the Commission showing that defendants committed numerous order violations. Appx. 5-22.¹

2. Whether the district court abused its discretion in allowing a laches defense against the Commission. Appx. 16-18, 42-43.

3. Whether the district court erred in ruling that defendants were entitled to a defense of substantial compliance. Appx. 16-18, 43-46.

STATEMENT OF RELATED CASES AND PROCEEDINGS

Defendants' activities that gave rise to the underlying FTC action and Final Orders entered against them were also the subject of litigation brought by the Food and Drug Administration ("FDA"). *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547 (D.N.J. 2004), *aff'd*, 427 F.3d 219 (3d Cir. 2005). The Commission is not aware of any other previous or pending related cases in this Court or any other court or agency.

STATEMENT OF THE CASE

A. Nature of the Case, the Course of Proceedings, and the Disposition Below

This appeal arises from an action brought by the FTC in 2000 against

¹ "Appx." refers to the Joint Appendix filed simultaneously with this brief.

defendants for deceptive practices in violation of Section 5 of the FTC Act,² in connection with their marketing and sale of two products (BeneFin and SkinAnswer) that purportedly treated cancer. The case settled, and the district court entered Final Orders permanently enjoining defendants from making claims about the health benefits of any product unless they possess competent and reliable scientific evidence to substantiate those claims.

In January 2007, the Commission initiated this civil contempt action against defendants for their violations of the Final Orders in connection with their marketing of two other products, AdvaCAL and Fertil Male. An evidentiary hearing was held from April 20 to April 24, 2009. On August 11, 2009, the district court issued an order denying the contempt motion, finding that the Commission had failed to show clear and convincing evidence of order violations and holding that, even if defendants had violated the Final Orders in some respects, they were entitled to a defense of substantial compliance. The Commission seeks review of this order.

B. Facts and Proceedings Below

1. Background

Lane Labs-USA, Inc. ("Lane Labs") is a supplier of dietary supplements.

² Section 5 of the FTC Act prohibits, *inter alia*, "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C § 45(a).

Andrew Lane is the president of Lane Labs, as well as its director and sole shareholder. I. William Lane ("William Lane") is Andrew Lane's father and has served as a consultant to Lane Labs and promoted various of the company's products.³

In June 2000, the Commission filed an action in the United States District Court for the District of New Jersey against Lane Labs, Andrew Lane, William Lane, and another corporation, Cartilage Consultants, Inc. The Commission charged defendants with deceptive practices in violation of Section 5 of the FTC Act in connection with their marketing of two products – BeneFin, a dietary supplement containing shark cartilage, and SkinAnswer, a skin cream. The Complaint alleged that defendants had made unsubstantiated claims about the efficacy of these products as treatments for cancer; made false representations regarding the clinical evidence of the efficacy of these products; and made false representations regarding the Food and Drug Administration's evaluation of BeneFin.⁴ The defendants settled these claims, and on July 6, 2000, and September

³ William Lane also was the owner and president of Cartilage Consultants, Inc., which was a defendant in the underlying action.

⁴ In December 1999, the FDA sued Lane Labs for misbranding and falsely advertising BeneFin, SkinAnswer, and another product (MGN-3, made from rice bran and shiitake mushroom) as drugs in violation of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq*. In July 2004, the district court found against defendants, issued permanent injunctive relief, and ordered

26, 2000, U.S. District Judge William G. Bassler entered Stipulated Final Orders for Permanent Injunction against them.

Among other things, the Final Orders prohibit defendants, "in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale or distribution of any food, dietary supplement, or drug," from "mak[ing] any representation . . . expressly or by implication," about the effect or health benefits of such product, "unless, at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representations." Appx. 534, 553 (Paragraph III). "Competent and reliable scientific evidence" is defined as "tests, analyses, research, studies, or other evidence based on the experience of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." Appx. 531, 550. The Final Orders also prohibit defendants from "expressly or by implication, misrepresent[ing] the existence, contents, validity, results, conclusions, or interpretations of any test, study or research." Appx. 535,

defendants to pay restitution to consumers who had purchased those products. *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547 (D.N.J. 2004). Lane Labs appealed the district court's authority to grant restitution under the FDCA; and this Court affirmed the district court. *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219 (3rd Cir. 2005). Lane Labs subsequently entered into a settlement with the FDA.

554 (Paragraph IV).

In or around 2000, Lane Labs began selling a new product, AdvaCAL (also known as AAACa), a calcium supplement derived from superheated oyster shells with the addition of a specially processed sea algae ("heated algae ingredient" or "HAI"). This product was developed by a Japanese company (Fujix) and, apart for some studies conducted by a Japanese doctor, Dr. Takuo Fujita, was not yet well studied. Appx. 273 (Tr. 703-06).

Lane Labs marketed AdvaCAL through multiple channels, including print ads in national publications, the Internet, its CompassioNet product catalog, by direct mail, and on infomercials.⁵ Appx. 269-71, 356 (Tr. 689-95, 924). In their advertising and marketing materials, defendants made numerous claims about AdvaCAL, including:

- AdvaCAL is the only calcium that can increase bone density.⁶
- AdvaCAL has been clinically shown to increase bone density in the hip.⁷

⁵ William Lane appeared in these infomercials touting AdvaCAL's benefits, and was also featured in the CompassioNet catalog, print ads, and retail store displays promoting AdvaCAL. *See, e.g.*, Appx. 657 (PX 140); Appx. 835 (PX 537); Appx. 1237 (DX 7 at LX000348).

⁶ See, e.g., Appx. 779 (PX 390); Appx. 836 (PX 537); Appx. 881 (PX 586).

⁷ See, e.g., Appx. 674 (PX 160); Appx. 796 (PX 477).

- AdvaCAL is three to four times more absorbable than other calcium supplements.⁸
- AdvaCAL is comparable or superior to prescription drugs to treat osteoporosis.⁹

These claims of uniqueness and superiority allowed Lane Labs to price AdvaCAL, not as just another calcium supplement, but as a "clinically proven Osteoporosis Fighter (with bone building results on par with prescription pharmaceuticals)." Appx. 897 (PX 589) ("Our AdvaCAL (tm) calcium has a suggested retail of \$39.95.... Calciums in the U.S. sell for about \$6.00; that is not our competitive set.").

Defendants made these representations notwithstanding that they were apprised on numerous occasions that many of their advertising claims lacked any support or distorted the findings of scientific research. At the outset, Andrew Lane retained Dr. Robert Heaney, a leading authority on calcium and osteoporosis, to review Dr. Fujita's research regarding AAACa. Appx. 135 (Tr. 263-64). Dr. Heaney did so, and informed Andrew Lane that, although this research showed that AAACa was absorbable, it did not support claims that AAACa is superior to other

⁸ See, e.g., Appx. 811 (PX 477); Appx. 840 (PX 537).

⁹ See, e.g., Appx. 812 (PX 477); Appx. 897 (PX 589).

calcium products. Appx. 717-30 (PX 243). Indeed, Dr. Heaney cautioned, "Advertising that claimed superiority without more convincing evidence than is now provided . . . would invite challenge by either the FTC or the Better Business Bureau." Appx. 730 (PX 243 at p. 14).

Lane Labs subsequently retained Dr. Heaney to test the absorbability of AAACa compared to another calcium product, CitraCal (calcium citrate), hoping to obtain substantiation for their superiority claims. Appx. 136 (Tr. 265-67). That study did not support defendants' claims either – to the contrary, it found that the calcium citrate was better absorbed than AAACa. Appx. 141 (Tr. 286); Appx. 731-42 (PX 244).¹⁰ Notwithstanding these results, defendants proceeded to market AdvaCAL as superior to all other calcium products, including calcium citrate.

Even Dr. Fujita himself cautioned against reliance on his studies of AAACa as support for certain of defendants' advertising claims. For example, Dr. Fujita made it clear that he did not have data to support defendants' claim that AAACa increased bone density in the hip. Appx. 587 (PX 36). Dr. Fujita also informed Andrew Lane that he was "not comfortable with the reliability" of the data from

¹⁰ The results of this study were highly statistically significant. App. 140 (Tr. 286-87). Lane Labs subsequently commissioned another study to compare AAACa to calcium citrate, but that study found that "[w]hile there was a trend favoring AAACa, . . . there was no statistically significant difference between the impact on bone resorption of AAACa and calcium citrate." Appx. 599 (PX 55).

one of his studies that defendants cited as a basis for claims that AdvaCAL outperformed other calcium products in reducing fracture rates. Appx. 586 (PX 34). A consultant retained by Lane Labs to review this data confirmed that "the numbers in Fujita's study are so small (I know you don't want to hear this) that none of his numbers are really meaningful." Appx. 678 (PX 181). Defendants disregarded these warnings as well, and continued to claim that AdvaCAL had been proven to be uniquely beneficial and superior to all other calcium supplements.

In late 2003, Lane Labs began marketing another product – Fertil Male – which contains a Peruvian plant root, *Lepidium meyenii*, also known as maca. Appx. 361-62 (Tr. 946-48). Lane Labs' promotional materials claimed that Fertil Male has been "clinically shown to promote male health – including healthy semen production, sperm count, and sperm motility;"¹¹ "optimize[s] male fertility;"¹² and can cause sperm count to "skyrocket" in as little as a month.¹³ Here as well, Lane Labs made these claims notwithstanding that the scant available research on maca was of questionable reliability and certain of their claims lacked any support at

- ¹² See, e.g., Appx. 877 (PX 572).
- ¹³ See, e.g., Appx. 776 (PX 386); Appx. 786 (PX 390).

¹¹ See, e.g., Appx. 776 (PX 386).

all.14

2. The Civil Contempt Proceedings

The Commission initiated the instant contempt proceeding in January 2007, filing a motion in the district court to show cause why the defendants should not be found in contempt for violating the Final Orders entered by Judge Bassler in 2000. The Commission alleged that defendants had disobeyed Paragraphs III and IV of the Stipulated Order by making claims regarding AdvaCAL and Fertil Male that were not supported by competent and reliable scientific evidence, and by misrepresenting the results of studies relating to these products.¹⁵ The Commission sought a monetary contempt award to compensate consumers who, relying on defendants' unsupported claims and misrepresentations, purchased these products.

An evidentiary hearing was held before Judge Cavanaugh on April 20 to April 24, 2009. The judge limited the hearing to the issue of liability, putting off

¹⁴ See Appx. 438-39 (Tr. 1146-49) (defendants' expert testified that rat studies did not support claim that Fertil Male had been "clinically shown" to increase sperm count, motility, and semen production, and there is no support for the claim that product can cause sperm count to "skyrocket" in one month); Appx. 2828 (DX 22 at LX001370) (authors of 9-person human study cautioned that "the number of subjects was insufficient for a valid conclusion").

¹⁵ The Commission also alleged that defendants had failed to comply with their obligations to maintain records regarding all of the claims made in their advertisements, as required by Paragraph IX of the Final Orders; however, the Commission is not pursuing that issue in this appeal.

the presentation of evidence of consumer injury for a later time, should defendants be found to have violated the Stipulated Order. Appx. 365 (Tr. 962). Each side presented live testimony by two expert witnesses: for the Commission, Dr. Heaney addressed the substantiation relating to AdvaCAL, and Dr. Niederberger addressed the substantiation relating to Fertil Male; while defendants' experts Dr. Holick testified concerning AdvaCAL, and Dr. Seibel testified concerning Fertil Male. The parties also presented live testimony of several fact witnesses, including defendant Andrew Lane and Jennifer Morganti (formerly employed by Lane Labs to check the substantiation for its advertising claims),¹⁶ and deposition testimony of several witnesses, including William Lane and Dr. Fujita.

Not surprisingly, the parties' experts expressed differing views on many subjects, including the appropriateness of defendants' reliance on studies that, for example, had statistically insignificant results, lacked a placebo control, lacked a sufficient number of subjects, or suffered high drop out rates. (Generally speaking, the Commission's experts said that such studies were not sufficiently "competent and reliable;" and defendants' experts said that, while those studies were not ideal, defendants were justified in relying on them.) Defendants experts did not attempt

¹⁶ Ms. Morganti (formerly Jennifer Nissen) also played a role in marketing Lane Labs' products, and was featured prominently in various of defendants' promotional materials for AdvaCAL. *See, e.g.*, Appx. 759 (PX 338); Appx. 823 (PX 506).

to justify all of defendants' advertising claims challenged by the Commission, however; and in many instances the Commission's evidence that such claims lacked substantiation was undisputed. Indeed, Andrew Lane himself admitted to numerous order violations. For his part, William Lane admitted that he took no steps to verify that the claims he made on infomercials promoting AdvaCAL were substantiated, but merely relied on what Dr. Fujita told him about the product.¹⁷

On August 11, 2009, the district court issued an opinion and an order denying the contempt motion, finding that the Commission had failed to sustain its burden of proving by clear and convincing evidence that defendants violated the Final Orders. Appx. 4 (Order); Appx. 5-22 (Opinion). In the court's view, this case boiled down to a "battle of the experts," Appx. 17, and although the court found that all four experts were credible and knowledgeable in their respective fields, Appx. 14, it felt that the Commission's experts (specifically, Dr. Heaney) applied too exacting a standard in evaluating the studies that defendants relied upon as support for their advertising claims, Appx. 10.

The court specified that "[o]f critical importance" to its decision was the fact that Dr. Heaney agreed that AdvaCAL is "a good source of calcium," and "[n]either of the FTC's experts stated that the supplements marketed by Lane Labs

¹⁷ See Appx. 652-56 (PX 137 at 46-64).

are not effective or constitute a health risk to the public." Appx. 17. In the court's view, defendants "did what they were supposed to do" under the Final Orders, by obtaining evidence that the products in question were "efficacious" and "consult[ing] experts who opined that the research supporting the product and the product itself were good." Appx. 18. Although the court recognized that defendants' ads contained misinformation, it found that these "errors" did not amount to order violations because the "overall impression" created by defendants' ads was that the products were "good products and will most likely help the people who take them," and this was supported by expert testimony. Appx. 19.

Furthermore, the court found that, even if defendants violated the Final Orders in some respects, they were entitled to a defense of substantial compliance, because they "thought they were compliant and undertook significant efforts to be compliant," Appx. 21, including hiring a compliance officer, seeking expert advice, and submitting compliance reports to the Commission, Appx. 20. It would be "fundamentally unfair," the court stated, for the Commission to penalize defendants for order violations "after years of not advising them of any compliance issues," particularly given that "the FTC provides no evidence that consumers have complained that they were physically harmed by the use of either supplement." Appx. 21-22. Accordingly, the court entered an order denying the Commission's motion to find defendants in contempt of the Final Orders. Appx. 5.

The Commission field a timely notice of appeal from this order on October 5, 2009. Appx. 1.

SUMMARY OF ARGUMENT

The district court abused its discretion in denying the Commission's motion to find defendants in contempt of the Final Orders for making unsubstantiated claims and misrepresenting the results of studies in their advertising of AdvaCAL and Fertil Male, because the court failed to consider the specific advertising claims challenged by the Commission. The court mistakenly viewed this contempt proceeding as merely involving a dispute about defendants' claims that these products had beneficial effects. The claims that the Commission principally challenged with regard to AdvaCAL, however, were not claims of the product's general efficacy, but rather claims of the product's superiority over other products. The Commission presented undisputed evidence – which the court erred in ignoring – that defendants made numerous unsubstantiated claims regarding AdvaCAL's purported superiority, and violated the Final Orders as well in their advertising of Fertil Male. (Part I, infra.)

The district court also erred because it fundamentally misconstrued the scope of the Final Orders as merely prohibiting defendants from making

unsubstantiated claims about the general health benefits of products. Contrary to the court's narrow reading, the Final Orders do not only prohibit entirely made up claims that a product has health benefits. They also prohibit defendants from making exaggerated claims about the proven health benefits of products (even generally beneficial products) or misrepresenting what studies of the products actually show – which is precisely the type of order violations that the Commission demonstrated here. (Part II, *infra*.)

The district court also erred as a matter of law in ruling that defendants were entitled to a defense of substantial compliance because they took various steps to be compliant, including submitting compliance reports to the Commission, and it would be "fundamentally unfair" for the Commission to penalize defendants after years of failing to notify them of any compliance problems. The district court's "fundamental fairness" rationale is nothing more than a laches defense, which the Supreme Court and the Courts of Appeals have held is not cognizable in government civil enforcement action. (Part III, *infra.*) The court also erred in applying a substantial compliance defense, because it failed to address whether defendants' violations were "technical or inadvertent," as the second prong of the defense requires, and the evidence undisputably showed that defendants' violations were neither technical nor inadvertent. (Part IV, *infra.*)

STANDARD OF REVIEW

This Court's "review of the denial of a contempt motion is for abuse of discretion by the district court." *Roe v. Operation Rescue*, 54 F.3d 133, 137 (3rd Cir. 1995). Reversal is appropriate "where the denial is based on an error of law or a finding of fact that is clearly erroneous." *Id.*; *Harley-Davidson, Inc. v. Morris*, 19 F.3d 142, 145 (3rd Cir. 1994).

ARGUMENT

I. THE DISTRICT COURT ABUSED ITS DISCRETION IN FAILING TO CONSIDER THE SPECIFIC ADVERTISING CLAIMS CHALLENGED BY THE COMMISSION.

The district court erred in denying the Commission's motion to find defendants in contempt of the Final Orders for making unsubstantiated claims and misrepresenting the results of studies regarding AdvaCAL and Fertil Male, because the court failed to consider the actual advertising claims challenged by the Commission in this proceeding. The court's repeated observations that AdvaCAL and Fertil Male were shown to be "good products," and that the Commission failed to establish that these products were ineffective or harmful to the public, Appx. 17-19, indicate that the court viewed this as a dispute about whether defendants were justified in claiming that these products had beneficial effects in general. The court, however, was mistaken. Defendants did not merely claim that their products were "good" or had beneficial health effects. They claimed, among other things, proven superiority to other products; identified specific measures of results that consumers could expect to see; and touted findings from "clinical studies" that did not exist. These are the claims that the Commission alleged violated the Final Orders, and these are the claims that the district court was required to address. Characterizing this proceeding as a "battle of the experts" did not relieve the district court of its obligation to evaluate the evidence regarding each of these claims, because defendants' experts did not attempt to justify all of defendants' advertising claims challenged by the Commission. Indeed, with regard to many of these claims, the evidence was undisputed that defendants lacked substantiation and misrepresented the results of studies.

A. The Court Ignored Undisputed Evidence Showing That Defendants Violated the Final Orders In Their Marketing Of AdvaCAL.

Because the court below focused entirely on defendants' general claims of efficacy for AdvaCAL (whether it was shown to be a good source of calcium), rather than the claims at the heart of the Commission's case – principally, defendants' superiority claims – the court ignored undisputed evidence showing that defendants lacked substantiation for many of their claims regarding AdvaCAL. The court's failure to find a violation in the face of this uncontroverted evidence amounts to an abuse of discretion.

1. Defendants lacked substantiation for the claim that "only" AdvaCAL can increase bone density.

There was undisputed evidence that defendants lacked substantiation for their claim – widely disseminated in their marketing materials throughout the period 2000 to 2006 – that AdvaCAL is the "only" calcium product that can increase bone density. *See* Appx. 881 (PX 586) ("Clinical studies show that AdvaCAL does what no other calcium does: actually increase bone density in women."); Appx. 836 (PX 537) (William Lane states on infomercial that AdvaCAL is the "only calcium I know of where you can actually increase bone density"); Appx. 805 (PX 477) ("Other calcium supplements cannot increase bone mass. AdvaCAL can."); Appx. 779 (PX 390) ("It's been nearly ten years and the other calciums still cannot build bone density. Meanwhile, AdvaCAL and AdvaCAL Ultra are even better.")

As Dr. Heaney explained, however, once absorbed into the intestine, different calcium salts lose their unique attributes and share the same benefits of calcium generally – including the ability to increase bone density. Appx. 137, 141 (Tr. 270-71, 286-88). Thus, this claim of uniqueness is false. Indeed, Jennifer Morganti, the former Lane Labs employee who was for a period of time responsible for verifying the substantiation for the ad claims, candidly admitted there is a general consensus that all forms of calcium can build bone density and "[t]o say that no other calciums can build bone is probably not true." Appx. 481 (Tr. 1317-18). Ms. Morganti further testified that Andrew Lane surely knew this because charts developed and used by Lane Labs in its advertising showed that other forms of calcium, not just AdvaCAL, can build bone density. *Id*. (Tr. 1318).¹⁸

At the hearing, Andrew Lane sought to justify the claim that AdvaCAL has the unique ability to increase bone density by asserting that, while other forms of calcium have been shown to increase bone mineral density ("BMD") against a placebo, only AdvaCAL has been shown to "build bone" in the sense of increasing BMD from baseline value. Appx. 382 (Tr. 1029-30). But even if one accepts defendants' definition of the term "build bone" at face value, their advertising claims that AdvaCAL is unique in this sense are demonstrably false. The Commission's evidence showed that, contrary to defendants' contention, studies of other forms of calcium have demonstrated increases in bone density from baseline value. Appx. 153 (Tr. 333-36); Appx. 748 (PX 258, Table 4); Appx. 755 (PX 261, Figs. 1 & 2). Defendants' expert did not dispute this evidence, and the court made

¹⁸ See also Appx. 630 (PX 80) (report prepared by consultant for Lane Labs noted that other forms of calcium had been found to increased bone density).

no findings regarding this crucial issue.

2. Defendants lacked substantiation for the claim that AdvaCAL has been shown in clinical tests to increase bone density in the hip.

Defendants also made the unsubstantiated claim that clinical tests show that AdvaCAL increases bone density in the hip. In one widely disseminated direct mailing, for example, defendants touted AdvaCAL's purported superiority to other calcium products as follows: "AdvaCAL is so advanced, it does what other calciums don't even dare to claim. In clinical tests [AdvaCAL] has been shown to actually increase bone density – even in the critical hip bones " Appx. 796 (PX 477). *See also* Appx. 674 (PX 160) ("AdvaCAL is the advanced calcium supplement shown in clinical tests to increase bone density – even in the critical bones of hip and spine.").

It was undisputed, however, that defendants lacked substantiation for this claim. Andrew Lane himself admitted, "There are no clinical studies on AdvaCal in the hip. . . . [W]e can't verify that statement." Appx. 288-89 (Tr. 765, 769). *See* Appx. 587 (PX 36) (in response to 2001 inquiry from Lane Labs asking "if we had data to show BMD increases in hip," Dr. Fujita "clarified that we do not."). Ms. Morganti concurred: "There was no substantiation for [the claim of] a clinical trial that showed increased bone density in the hip." Appx. 482 (Tr. 1324).

Defendants' expert, Dr. Holick, likewise testified that there was "no dispute" in his mind that Lane Labs had no clinical research showing that AdvaCAL increases bone density in the hip. Appx. 351 (Tr. 905).¹⁹ The district court, in its ruling, entirely ignored defendants' lack of substantiation for this claim.

3. Defendants lacked substantiation for the claim that AdvaCAL is three to four times more absorbable than other calcium supplements.

In infomercials, on the internet, in product catalogs, in direct mail pieces, and in magazine advertisements disseminated from 2000 through 2006, defendants claimed that AdvaCAL is anywhere from three to four times more absorbable than other calcium products. Many of these advertisements touted AdvaCAL's superiority specifically compared to calcium carbonate (the type of calcium found in the antacid Tums and other popular calcium supplements). *See, e.g.*, Appx. 840 (PX 537) (infomercial states that "AdvaCAL has been clinically shown to be three times more absorbable than other calciums"); Appx. 850-51 (PX 537) (in infomercial William Lane states that the calcium in antacid tablets "is so hard, your body cannot absorb it, it's like a rock."); Appx. 811 (PX 477) (AdvaCAL "is absorbed four times better than typical calcium carbonate supplements"); Appx.

¹⁹ The only studies involving AAACa that measured the hip site were animal studies, which, by definition, are not "clinical" (*i.e.*, human) studies. Appx. 150, 161 (Tr. 321, 367-68).

820 (PX 502) (AdvaCAL "is absorbed four times better than typical calcium carbonate/coral calcium supplements"). Defendants used these claims of superiority to justify AdvaCAL's higher price: "AdvaCAL is not the cheapest calcium supplement, but . . . it is the best." Appx. 784 (PX 390). The Commission showed below that there is no substantiation for these claims, yet the district court wholly ignored this evidence in its ruling.

Andrew Lane initially asserted that Lane Labs relied on animal studies for this superiority claim. Appx. 570 (PX 17 at ¶ 13).²⁰ The evidence was undisputed, however, that these studies do not support this claim because – as both Dr. Heaney and Dr. Fujita testified – the manner in which the calcium was administered to the animal subjects was "unphysiological." Appx. 715-16 (PX 206 at 262-63); Appx. 149-51 (Tr. 318-25). (In one study, for example, the gut loop of rats was tied off and they were forcibly fed massive, probably toxic, amounts of calcium. Appx. 149 (Tr. 318).) Indeed, Dr. Fujita stated unequivocally that defendants' claim that AdvaCAL is three times more absorbable than other calciums is based on an "unjustified extrapolation" of the rat study. Appx. 637 (PX 126).

More importantly, the expert testimony demonstrated that under normal

²⁰ As discussed in the preceding footnote, animal studies, by definition, do not support claims that AdvaCAL has been "clinically" shown" (*i.e.*, in human trials) to be three times more absorbable that other calcium supplements. *See* Appx. 149-50 (Tr. 320-21).

circumstances it would be impossible for AdvaCAL to be three to four times more absorbable than calcium carbonate. As Dr. Heaney explained, the absorption value of a typical calcium carbonate supplement is in the range of 30% to 35%. For AdvaCAL to be three times more absorbable, it would have to have an absorption value of 90%; to be four times more absorbable, it would have to have an absorption value of 120%. It is physiologically impossible, however, for human bodies to absorb even 80% of a calcium source (and mathematically impossible to absorb 120%). Appx. 148-49 (Tr. 316-17).

Dr. Holick did not dispute – indeed, he agreed – that under normal circumstances, given normal absorption of calcium carbonate, it would be impossible for AdvaCAL to be three to four times more absorbable than calcium carbonate. Appx. 3631 (DX 32 at ¶ 47). He stated, however, that "it is conceivable" that this claim could be true (though he did not commit to the claim's actual truth) as to individuals suffering from a medical condition known as achlorhydria (the inability to make stomach acid), because calcium carbonate has been found to be poorly absorbed by achlorhydric subjects when taken on an empty stomach. Appx. 3632 (DX 32 at ¶ 48); Appx. 341 (Tr. 866).²¹ But it is

²¹ The study showed that, when the subjects took the calcium carbonate with food, absorption completely normalized. Appx. 151 (Tr. 325-26). It is worth noting that Lane Labs recommends that AdvaCAL be taken with a meal. Appx. 386 (Tr. 1047).

entirely unknown how AdvaCAL would perform in such circumstances compared to calcium carbonate or any other calcium. As Dr. Holick conceded, and Andrew Lane admitted, AdvaCAL itself has never been tested on patients who are achlorhydric or under fasting conditions. Appx. 345, 386 (Tr. 881-82, 1046). Thus, defendants possessed no actual substantiation for this claim (as the Final Order requires), just mere speculation that the claim could "conceivably" be true.

Moreover, defendants' contention that the achlorhydria study involving calcium carbonate substantiates their "three (or four) times more absorbable" claim is belied by Dr. Holick's testimony that he actually recommends Tums to his patients with achlorhydria: "I tell my patients that even if you have achlorhydria, if you take Tums and you chew it, it's automatically biovailable even though it's calcium carbonate because you've already broken it down." Appx. 351 (Tr. 904, 907). Dr. Heaney confirmed that defendants' claim that the body cannot absorb calcium carbonate is "substantially inaccurate for any properly formulated calcium supplement or antacid product." Appx. 148 (Tr. 315-16).

Finally, defendants asserted that their claim of "three (or four) times more absorbable" was justified, if not as to calcium carbonate, then at least as to calcium oxalate (the calcium in spinach), because: (a) a study has shown that calcium carbonate is absorbed three times better than calcium oxalate; (b) Dr. Fujita found that AAACa is better absorbed than calcium carbonate;²² therefore (c) AdvaCAL is at least three times more absorbable than calcium oxalate. Even assuming, for the sake of argument, that such a syllogism might substitute for the "competent and reliable scientific evidence" required by the Final Orders, it does not support the advertising claims made by defendants here: that AdvaCAL has been shown to be three to four times more absorbable than other calcium *supplements* (and, specifically, calcium carbonate). Whether AdvaCAL is a better source of calcium than spinach is irrelevant, because the type of calcium in spinach is so poorly absorbed that it is not used in calcium supplements. Appx. 137 (Tr. 271).

4. Defendants lacked substantiation for the claim that AdvaCAL is comparable or superior to prescription osteoporosis drugs.

Defendants did not merely advertise AdvaCAL as superior to other calcium supplements. Many of their promotional materials also claimed that AdvaCAL was at least as effective as or better than prescription drugs for the treatment of osteoporosis. *See* Appx. 812 (PX 477) ("Natural bone-building nutrients [in AAACa] work better than prescription drugs" and "AAACa works as well or better than these expensive drugs, and without the substantial side effects and risks");

²² Andrew Lane admitted that "[w]hile Dr. Fujita has opined that AdvaCAL is more absorbable than other calcium forms, he has not quantified it as 3 times." Appx. 570 (PX 17 at ¶ 13).

Appx. 667 (PX 142) (AdvaCAL is "clinically proven to fight osteoporosis without the side effect of drugs"); Appx. 820 (PX 502) (in contrast to hormone replacement therapy, AdvaCAL "has the power to prevent and reverse bone loss – without dangerous hormonal manipulation"); Appx. 864 (PX 537) ("all you have to do" to prevent hip fractures and pain "is take your AdvaCAL"); Appx. 897 (PX 589) ("We are selling an [sic] clinically proven Osteoporosis Fighter (with bone building results on par with prescription pharmaceuticals) without the risks of side effects."). The value to defendants of such claims is clear: as a consultant retained by Lane Labs observed, "Because [AdvaCAL] is so much more expensive than other calcium supplements, it may be more useful in marketing materials to compare AdvaCAL (cost, efficacy, side effects, risks) with osteoporosis drugs." Appx. 631 (PX 80).

Dr. Heaney testified that not only is there no competent and reliable scientific evidence substantiating the claim that AdvaCAL is as effective as prescription drugs for treating osteoporosis, Appx. 160, 170 (Tr. 361-62, 403-04),²³ the claim is "inaccurate and potentially dangerous." Appx. 171 (Tr. 405).²⁴ Dr.

²³ It was undisputed that AdvaCAL has never been tested against any prescription drug. Appx. 170 (Tr. 404).

²⁴ Dr. Heaney further testified that there is no basis for the claim that calcium could substitute for hormone replacement therapy, and in perimenopausal women, in particular, bone loss is principally for hormonal reasons, not because of

Holick did not dispute this; in fact, he did not address this advertising claim at all. Defendants offered no substantiation for this claim; they simply denied that they had ever marketed AdvaCAL as a substitute for prescription osteoporosis drugs, pointing to statements in certain of their ads urging women being treated for osteoporosis to take AdvaCAL in addition to their prescription drugs. But the fact that some of their ads said that consumers taking prescription drugs should also take AdvaCAL does not negate the clear evidence showing that many other of defendants' advertising materials promoted AdvaCAL as a side-effect free, equally effective alternative to prescription osteoporosis drugs.

One of the boldest of these claims ("works as well or better than these expensive drugs, and without the substantial side effects and risks," Appx. 812 (PX 477), was contained in an article entitled "The Battle for Your Bones," initially published in a health newsletter. Appx. 808-13 (PX 477).²⁵ Defendants argued below that they could be not held accountable for this claim because they did not

calcium deficiency. Appx. 160 (Tr. 361-62).

²⁵ This article came about after Andrew Lane contacted the newsletter's editor, Monica Reinagel, in 1999 to pitch a story about AdvaCAL, a "revolutionary new product from Japan that has been clinically shown to actually build postmenopausal bone density, without the side effects of hormonal drugs or supplements." Appx. 892 (PX 588). Andrew Lane later retained Ms. Reinagel as a consultant to review calcium studies for Lane Labs. Appx. 376 (Tr. 1005-06).

author that article.²⁶ Andrew Lane admitted, however, that "[w]e used that publication extensively" in marketing AdvaCAL – among other things, by including it in direct mailings to consumers and in retail store display cases. Appx. 450 (Tr. 1194-96). Defendants not only used that article to persuade consumers to buy AdvaCAL, they held it out as their own: in an infomercial for AdvaCAL, for instance, William Lane urged consumers to call and ask for this article, describing it as one of "our" "informative special reports." Appx. 862, 872-73 (PX 537). Having done so, defendants cannot now disclaim responsibility for this unsubstantiated claim.

5. Defendants distorted the research on AdvaCAL and other forms of calcium.

Undisputed evidence also shows that, to support their claims of AdvaCAL's superior performance, defendants repeatedly misrepresented and distorted the results of calcium studies. Many of these violations occurred in connection with the claims discussed above. For example, defendants represented that AdvaCAL's superiority was demonstrated by "clinical" (that is, human) studies, when in fact the studies in question were animal studies; and defendants represented that

²⁶ Defendants' argument is contravened by Paragraph VI of the Final Orders, which specifies that defendants may use third-party literature in promoting their products only "when its use is not false, deceptive or misleading." Appx. 536, 555.

AdvaCAL had been proven to be as effective as prescription osteoporosis drugs, when in fact AdvaCAL had never been tested against the drugs in question. *See* notes 19, 20, and 23 and accompanying text, *supra*.

The record shows numerous other instances in which defendants misrepresented the results of studies. Among them:

 Defendants repeatedly used a chart entitled "2-Year Spinal Bone Density Changes" in their ads to graphically illustrate AdvaCAL's purported superiority to other types of calcium. *See*, *e.g.*, Appx. 766 (PX 347). It was undisputed that the column in this chart pertaining to calcium hydroxyapatite was derived from a study of radial bone density – not spinal bone density.²⁷ This was no mere inadvertent error. As Ms. Morganti explained, "it was the only study that we had on that particular ingredient, and so we utilized it, even though it wasn't exactly a spinal change." Appx. 479 (Tr. 1311). *See also* Appx. 353 (Tr. 913-914) (Andrew Lane admitted that the data "shouldn't be there").

²⁷ As Dr. Heaney explained, one cannot draw any conclusions about spinal bone density from a study measuring radial bone density. Appx. 164-65 (Tr. 380-81). Defendants were fully aware of this fact. *See* Appx. 632 (PX 80) (report prepared by consultant for Lane Labs cautioned, "when comparing numbers, it is important to compare 'apples to apples' . . . [T]he effect of calcium supplementation at these [different skeletal] sites may vary greatly.").

- Defendants claimed that AdvaCAL "has been clinically shown to increase bone density by as much as 10% *per year*." *See, e.g.*, Appx. 677 (PX 165) (emphasis added). It was undisputed, however, that the studies relied upon by defendants in support of that claim did not show increases in bone density of that magnitude year after year. Appx. 480 (Tr. 1314-15).²⁸
- Another chart that defendants used repeatedly in their ads purported to show "Bone Density Increases with AdvaCAL" in different groups of study subjects measured at the one-year mark and the two-year mark. *See, e.g.*, Appx. 767 (PX 347); Appx. 814 (PX 477). But Andrew Lane admitted that in some instances no 12-month data was reported, so "to fill in the blanks" he included data from 6-month and 18-month intervals and labeled them 12-month data. Appx. 462 (Tr. 1242).²⁹

²⁸ Dr. Heaney testified that the likelihood that an individual (much less a group of individuals) could exhibit bone density increases of 10% per year "is essentially zero" (unless they were patients with primary hyperthyroidism and advanced bone disease). Appx. 169 (Tr. 397-98).

²⁹ As Dr. Heaney explained, one cannot assume that a bone density measurement at the 6-month mark is an indication of what the measurement will be at the 12-month mark, because, after an initial rise, bone density increases from calcium supplementation follow a downward-sloping curve – a point that Dr. Heaney explained to Andrew Lane in his 1999 report for Lane Labs. Appx. 159, 168 (Tr. 358-59, 394); Appx. 722 (PX 243).

Thus, there was ample undisputed evidence that defendants repeatedly misrepresented study results to bolster their claims of AdvaCAL's purported superior performance. The district court failed to give this evidence any weight, however, because it mistakenly treated this case as a challenge to defendants' representations that AdvaCAL was a "good product."³⁰

B. The Court Ignored Undisputed Evidence Showing That Defendants Violated The Final Orders In Their Marketing Of Fertil Male.

The Commission also presented undisputed evidence that defendants

violated the Final Orders in connection with their marketing of Fertil Male. The

clearest example of this is Lane Labs' claim that Fertil Male can cause sperm count

to "skyrocket" in as little as one month. Alongside a photograph a young family of

four (including a baby), Lane Labs' product catalog contained the following text:

Husband + Wife + Fertil Male = One big happy family!

Kelli and Joe Faber (above) love being parents. It took them 2 years and a lot of trying to have Cassandra (now 4). So when they started thinking about having another baby, Kelli suggested something different. A Lane Labs employee, Kelli had read the research on Fertil Male. . . . Kelli brought some home for Joe to try. The results were dramatic. In the first month, Joe's sperm count skyrocketed.

³⁰ The court made the passing observation that "some things slipped through the cracks" and "errors were made over a number of years." Appx. 19. But the testimony of Andrew Lane and Ms. Morganti unquestionably demonstrates that these misrepresentations of study results were not mere "slips" – rather, defendants made deliberate choices to fudge data from relevant studies to portray AdvaCAL in a more favorable light.

And less than a year later, baby Madeline made her appearance.

See, e.g., Appx. 776 (PX 386); Appx. 786 (PX 390).³¹

The expert testimony showed, however, that spermatogenesis (the time it takes for sperm to go from inception to emission) in human males is three months. Appx. 438 (Tr. 1145). Lane Labs' own expert conceded that there was no support in the studies cited by defendants for a biological mechanism suggesting that maca, the principal ingredient in Fertil Male, could affect sperm count in a shorter period. *Id.* (Tr. 1147-48). Yet the district court ignored this undisputed evidence as well.³²

II. THE COURT ERRED AS A MATTER OF LAW BECAUSE IT MISCONSTRUED THE FINAL ORDERS.

The district court erred not only because it failed to consider the specific advertising claims challenged by the Commission here, but also – more fundamentally – because it applied an unduly narrow reading of the Final Orders. The court's repeated emphasis on the Commission's failure to establish that

³¹ Although defendants denied that these ads – indeed, the product name itself – were meant to suggest that Fertil Male treats male infertility, that is the clear implication of this advertising. Notably, Lane Labs' expert testified that there is no competent and reliable scientific evidence that maca is a treatment for male infertility. Appx. 437 (Tr. 1144).

³² The district court also ignored Andrew Lane's admission that Lane Labs had no substantiation for its claim that Fertil Male "optimizes" male fertility, Appx. 877 (PX 572), although he professed to be unclear about exactly what "optimize" was supposed to mean in this context. Appx. 459 (Tr. 1231-32).

AdvaCAL and Fertil Male were not "good products," Appx. 17-19, and the Commission's failure to establish that these products physically harmed people, Appx. 17, suggests that the court interpreted the Final Orders as simply restricting defendants' marketing of products that have no demonstrable health benefits.³³ This narrow reading is contravened by the Final Orders' plain language, which broadly bars defendants from (i) making "*any claim*" concerning "the effect of such product . . . or about *any other health benefits* of such product," unless the defendants can adequately substantiate that claim; and (ii) "misrepresent[ing] the existence, contents, validity, results, conclusions, or interpretations of *any test, study or research.*" Appx. 534-35, 553-54 (emphasis added).

Contrary to the district court's view, these provisions do not simply prohibit defendants from making up claims about a products' beneficial effects "out of thin air." Appx. 18. They also prohibit defendants from over-reaching in their claims about products that may have some beneficial effects – from exaggerating the proven health benefits of such products or misrepresenting what studies of the

³³ The court erred as a factual matter in finding that the Commission's experts did not identify any health risk to the public. Appx. 17. Dr. Heaney testified that defendants' claim that AdvaCAL is as effective as prescription osteoporosis drugs for preventing bone fractures is inaccurate and potentially dangerous. Appx. 171 (Tr. 405). And Dr. Niederberger testified that, not only is there no evidence of a benefit from taking maca, "there's evidence to suggest that there might be harm." Appx. 259 (Tr. 647).

products actually show – which is precisely what defendants did here. Indeed, the FTC has often brought actions to stop such exaggerated claims about the health benefits of products, including products that are indisputably "good" products. *See, e.g., American Home Products Corp. v. FTC*, 695 F. 2d 681 (3rd Cir. 1982) (aspirin producer found to have violated the FTC Act by making unsubstantiated claims about its product's superiority to other products and misrepresenting the level of support for its product claims); *Kraft, Inc. v. FTC*, 970 F.2d 311 (7th Cir. 1992) (manufacturer of processed cheese found to have violated the FTC Act by misrepresenting the calcium benefit of its product compared to other products).

The district court's restrictive interpretation of the Final Orders is at odds with this case law as well as the plain language of the Final Orders, and thus is erroneous as a matter of law.

III. THE DISTRICT COURT ERRED AS A MATTER OF LAW IN DENYING THE FTC'S CONTEMPT MOTION ON GROUNDS OF "FUNDAMENTAL FAIRNESS."

Defendants argued below that, even if they were found to have violated the Final Orders, it would be unfair to hold them in contempt, because they disclosed their advertising and related substantiation in compliance reports to the Commission in 2001 and 2004, but the Commission waited until 2006 before informing them of its concerns.³⁴ Judge Cavanaugh made it clear at the outset of the evidentiary hearing that he found this argument to be compelling, cautioning the FTC's counsel that the agency "may be a day late and a dollar short," and "this is going to play a big part in my view as to what happens here." Appx. 63 (Tr. 56, 58). Indeed, that turned out to be the case. After giving short shrift to the Commission's considerable evidence demonstrating defendants' order violations, the judge ruled that, in any event, the Commission's failure to tell defendants sooner that their compliance efforts were inadequate precluded the Commission from now enforcing the Final Orders against them. Appx. 21.

The court's ruling directly contravenes well-established law that, "[a]s a general rule laches or neglect of duty on the part of the Government is no defense to a suit by it to enforce a public right or to protect a public interest." *Nevada v. United States*, 463 U.S. 110, 141 (1983) (internal quotation marks omitted); *United States v. Summerlin*, 310 U.S. 414, 416 (1940) ("It is well settled that the United States is not . . . subject to the defense of laches in enforcing its rights."); *Mudric v.*

³⁴ In fact, defendants were well aware that the absence of FTC action following their submission of a compliance report was not to be construed as FTC approval of their activities. In responding to a similar argument made (unsuccessfully) by Lane Labs in the related FDA litigation (*see* n. 4, *supra*), the Commission made it clear that "the absence of an enforcement action by the FTC is not necessarily an indication of the legality of any action or compliance with the terms of the Final Order." *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 3d at 572.

Attorney Gen. of the U.S., 469 F.3d 94, 99 (3rd Cir. 2006); United States v. Angell, 292 F.3d 333, 338 (2nd Cir. 2002); United States v. Hughes House Nursing Home, Inc., 710 F.2d 891, 895 (1st Cir. 1983); United States v. Ruby Co., 588 F.2d 697, 705 n.10 (9th Cir. 1978). As the First Circuit so colorfully explained, "it is not true that once a government agency smells a rat, the agency must exterminate it forthwith or allow it the run of the public's house in perpetuo." United States v. Michael Schiavone & Sons, Inc., 430 F.2d 231, 233 (1st Cir. 1970).

For example, in *United States v. Hughes House Nursing Home, Inc.*, First Circuit Judge (now Justice) Breyer rejected the defendant's argument that a sixyear delay should bar the government from bringing an action to recover Medicare overpayments, because "[a] virtually unbroken line of authority . . . holds that private defendants cannot assert laches against the government." 710 F.2d at 895. Likewise, in *United States v. Angell*, the Second Circuit rejected the defendant's argument that the Army Corps of Engineers should be precluded from challenging his construction of docks because the agency delayed action until four years after construction was completed. 292 F.3d at 338 ("laches is not available against the federal government when it undertakes to enforce a public right or protect the public interest"). And, in *Ohlhausen v. Comm'r of Internal Revenue*, 273 F.2d 23 (9th Cir. 1959), the Ninth Circuit rejected the defendant's argument that, had the IRS made its payment demands earlier, he would have incurred lesser penalties. *Id.* at 29 ("No such shift in responsibility can be sanctioned. Petitioner could have avoided all liability by complying with a statutory requirement which he should have known existed.").

The court below declined to characterize this as an issue of laches, stating that the Commission's failure to challenge defendants' advertising claims sooner was relevant as a matter of "fundamental fairness." In particular, the court was concerned with the fairness of the remedy sought by the Commission – an award to compensate for consumer injury, as measured by defendants' total receipts from sales of AdvaCAL and Fertil Male. But "fundamental fairness" is precisely what a laches (or equitable estoppel) defense is about: it is an argument that it would be unfair to penalize a defendant for conduct that the government has long left unchallenged.³⁵ The Supreme Court and Courts of Appeals, however, have flatly

³⁵ The argument that a defendant detrimentally relied on the government's inaction can be raised as a laches defense or an equitable estoppel defense. As this Court has explained, to sustain an argument that a government agency should be equitably estopped from pursuing an action, a defendant must show a misrepresentation and affirmative misconduct by the government. *Mudric*, 469 F.3d at 99. "[M]ere delay does not constitute 'affirmative misconduct' on the part of the Government." *Id. See United States v. Hemmen*, 51 F.3d 883, 892 (9th Cir. 1995) (rejecting laches defense out of hand, and rejecting equitable estoppel defense because defendant "raise[d] questions only as to what [the agency] failed to do . . . [not] affirmative misconduct going beyond mere negligence") (internal quotation marks omitted). Notably, defendants here have neither asserted nor demonstrated any misrepresentation or affirmative misconduct by the FTC.

rejected these equitable defenses against the government in civil enforcement actions. Moreover, the fairness of the compensatory award sought by the Commission has no bearing on the question whether the defendants are liable for violations of the Final Order.³⁶

Furthermore, the district court erred as a factual matter in finding that, prior to 2006, defendants had fully disclosed to the Commission their advertising claims for AdvaCAL and Fertil Male and the related scientific research. The record shows that defendants did not provide information relating to their marketing of Fertil Male until 2006. Appx. 364 (Tr. 956). With regard to AdvaCAL, defendants conveniently omitted from their compliance reports materials that would have risked alerting the Commission that serious questions existed about the substantiation for their superiority claims – including, most significantly, Dr. Heaney's report in which he advised Lane Labs that the Japanese studies of AAACa did not support their claims, and his subsequent study (commissioned by Lane Labs) which found that, contrary to defendants' claims of superiority, AdvaCAL was less absorbable than calcium citrate.³⁷

³⁶ As noted above, the district court decided to hear evidence on liability first, putting off the presentation of evidence concerning consumer injury for a later date.

³⁷ *Compare* Appx. 717-42 (PX 243 and 244) (Dr. Heaney's report and study for Lane Labs) *with* Appx. 955-2078 (DX 6, 7, and 8)(defendants' 2001, 1004, and

But even if defendants had provided these materials to the Commission prior to 2006, the Commission was not required to immediately commence litigation or forfeit its right to prosecute order violations, as the cases above make clear. The district court erred in holding otherwise.

IV. THE DISTRICT COURT ERRED AS A MATTER OF LAW IN APPLYING A DEFENSE OF SUBSTANTIAL COMPLIANCE.

The district also committed legal error in ruling that defendants' order violations were excusable on the theory that they had substantially complied with the Final Orders. Substantial compliance is a defense to contempt only when: (1) the defendant has taken "all reasonable steps" to comply with the court order, and (2) the violations of the order are "technical or inadvertent." *Robin Woods Inc. v. Woods*, 28 F.3d 396, 399 (3rd Cir. 1994); *General Signal Corp. v. Donallco, Inc.*, 787 F.2d 1376, 1379 (9th Cir. 1986). Although the district court found that defendants had taken reasonable steps to comply with the Final Orders, it failed to address whether defendants' violations were "technical" or "inadvertent," as the second prong of the defense requires. In fact, defendants' violations were neither technical nor inadvertent.

The district court found that defendants were entitled to a defense of substantial compliance because "Defendants thought they were compliant and

²⁰⁰⁶ compliance reports omitting Dr. Heaney's report and study).

undertook significant efforts to be compliant," Appx. 21, including hiring a compliance officer, seeking expert advice, and submitting compliance reports to the Commission. Appx. 20. It is settled law, however, that good faith is not a defense to civil contempt. *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 191 (1949) ("An act does not cease to be a violation . . . of a decree merely because it may have been done innocently."); *Robin Woods Inc.*, 28 F.3d at 399 ("good faith is not a defense to civil contempt"); *Harley-Davidson, Inc. v. Morris*, 19 F.3d at 148 ("willfulness is not a necessary element of civil contempt"). Furthermore, this Court has made clear that "good faith" is not the same thing as "inadvertent." *Robin Woods Inc.*, 28 F.3d at 399.

In *Robin Woods Inc.*, for example, the Court held that defendants were not entitled to a defense of substantial compliance, even though they had consulted with counsel regarding how to comply with the court order, had undertaken significant steps to comply with the order, and had acted without an intent to violate the order. The court order in question prohibited Mrs. Woods, a wellknown doll designer who had sold her business to another company, and her new employer from using her name to promote dolls. After consulting with counsel, who advised that Mrs Woods could continue to design dolls so long as she did so under a pseudonym, Mrs. Woods adopted a new professional identity and began creating a new line of dolls under that name. However, a letter to industry participants announcing this new line of dolls disclosed that Mrs. Woods was the dolls' true creator. The Court held that Mr. Woods and her employer were liable for violating the order, notwithstanding their significant good faith efforts to comply with the court order, because in the offending announcement they "consciously chose" to associate Mrs. Woods with the new line of dolls. *Id. See also Star Financial Services, Inc. v. AASTAR Mortgage Corp.*, 89 F.3d 5, 12-14 (1st Cir. 1996) (court held defendant in contempt for sending facsimiles with prohibited logo, notwithstanding defendant's good faith and substantial efforts to comply with injunction requiring it to cease use of infringing trade name).

Likewise, in the instant case, the fact that defendants may have taken steps to comply with the Final Orders as a general matter and in good faith believed that their activities were compliant does not entitle them to a defense of substantial compliance. Defendants still must show that their violations were technical and inadvertent. Here, the nature and scope of the order violations leave no doubt that defendants' transgressions were not merely technical or inadvertent. Defendants violated the core conduct provisions of the Final Orders; and they did so repeatedly, over many years, in connection with numerous separate advertising claims and two different products. The number and duration of defendants' violations alone distinguish this case from those cases in which courts have found substantial compliance. *See Vertex Distributing, Inc. v. Falcon Foam Plastics, Inc.*, 689 F.2d 885, 891-92 (9th Cir. 1982) (court found substantial compliance where plaintiff introduced evidence of only one violation, and defendants had taken steps to correct it before contempt proceeding was initiated); *Southern Ry. Co. v. Brotherhood of Locomotive Firemen & Enginemen,* 337 F.2d 127, 135 (D.C. Cir. 1964) (court found substantial compliance with order requiring railroad to employ firemen on all locomotives, where defendant was in compliance on all but 47 out of 42,000 trains, and majority of violations had occurred within first few days after the order was entered).

In this case, moreover, the evidence shows that defendants were informed on numerous occasions that the studies in question did not support various of their product claims, but they chose to disregard these warning and persist in making such claims. *See* pp. 7-9, *supra*. Under these circumstances, defendants' order violations cannot be deemed inadvertent. Indeed, given this evidence showing that defendants persisted in making product claims that their own experts and consultants advised against, the district court's finding that defendants took all reasonable steps to comply with the Final Orders (as the first prong of the substantial compliance defense requires) is clearly erroneous.

Because the district court erred in its application of the substantial compliance defense and failed to consider undisputed evidence showing that defendants' violations were a product of their deliberate choice to make claims about AdvaCAL and Fertil Male that were not adequately substantiated, the district court's order denying the Commission's contempt motion must be reversed.

CONCLUSION

For all the reasons stated above, appellant respectfully requests that this Court reverse the decision of the district court, and remand this case to the district court with instructions to enter an order granting the Commission's motion to find defendants in civil contempt of the Final Orders, and to conduct further proceedings on the issue of remedy.

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COMBINED CERTIFICATIONS

1. Bar membership – Because this brief is filed on behalf of an administrative agency of the United States, there is no bar membership requirement.

2. Word count – I certify that this brief complies with Fed. R. App. P. 32(a)(7)(B). It is proportionally spaced and contains 10,073 words, as counted by the WordPerfect word processing program.

3. Service upon counsel -- I hereby certify that, in addition service accomplished by the CM/ECF system, on December 16, 2009, I served a copy of the brief on appellees by overnight mail addressed to:

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4. Identical compliance of briefs – I certify that the text of the electronic brief, which was submitted to this Court, is identical to the paper copies that were served on this Court and on appellants.

5. Virus check – I certify that I have run a virus check on this brief and no virus was detected. I used Symantec AntiVirus rev. 4 (updated to December 14, 2009).

<u>s/ Michele Arington</u> Michele Arington