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

WILLARD K. TOM
General Counsel

JOHN F. DALY
Deputy General Counsel for Litigation

OF COUNSEL:

MICHELE ARINGTON
Attorney
Office of the General Counsel
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580
(202) 326-3157

ELSIE B. KAPPLER
CONSTANCE M. VECELLIO
AMANDA C. BASTA
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES

CASES **PAGE**

FEDERAL STATUTES

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 treaedlda

[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).

[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

26, 2000, U.S. District Judge William G. Bassler entered Stipulated Final Orders for PermanentyInjunction 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 competentyand reliable scientific evidence that substantiates the representations." Appx. 534, 553 (Paragraph III). "Competentyand 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 accurateyand 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. , 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. , 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]

[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

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

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

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 promot

---

[11] *See, e.g.*, Appx. 776 (PX 386).

[12] *See, e.g.*, Appx. 877 (PX 572).

[13] *See, e.g.*, Appx. 776 (PX 386); Appx. 786 (PX 390).

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

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*.)

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

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

[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

[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).

[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 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

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.

[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-

- 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).

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).

[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). only is

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

[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, *see*

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

---

[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

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.

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.

WILLARD K. TOM
General Counsel

JOHN F. DALY
Deputy General Counsel for Litigation

OF COUNSEL:

s/ Michele Arington
MICHELE ARINGTON
Attorney, DC Bar No. 434082
Office of the General Counsel
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580
(202) 326-3157

ELSIE B. KAPPLER
CONSTANCE M. VECELLIO
AMANDA C. BASTA
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Dated: December 16, 2009

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:

Jack Wenick, Esq.
Sills Cummis & Gross P.C.
One Riverfron Plaza
Newark. NJ 07102

Paul F. Carvelli, Esq.
McCusker Anselmi Rosen & Carvelli, P.C.
210 Park Avenue, Suite 301
Florham Park, NJ 07932

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 wTji6 TclA2Mt wer 0003 tiV0 -1.150-1.7460006 Tc-.0017 Tw(filed [(SpAnaS)tce-iefs – I certi