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-Appellees,

and

CARTILAGE CONSULTANTS, INC.,
Defendant.

On Appeal from the United

TABLE OF AUTHORITIES

CASES **PAGE**

ARGUMENT

[1] "LL Br." refers to the Brief of Defendants-Appellees Andrew J. Lane and Lane Labs-USA, Inc. Because I. William Lane joins in the factual recitations and legal arguments made in that brief, the Commission will refer to matters asserted in that brief as, collectively, defendants' assertions. *See* Brief of Defendant-Appellee I. William Lane ("WL Br.") at 3, n.2.

[2] Although defendants suggest that there is something inappropriate about the amount of discovery taken by600 0.0000 TD(thi)Tj14.1600 0.0000 TD(ng i)Tj14.8800 0.00

form of calcium, but it did not substantiate defendants' claims about AdvaCAL's purported superiority. This research, which Andrew Lane asked Dr. Heaney to evaluate before Lane Labs began marketing AdvaCal (also known as "AAACa), consisted of:

- a paper showing that AAACa produced a bone benefit, but providing no comparative data for other calcium sources;
- a study showing little difference between calcium carbonate and AAACa;
- a paper cu0000 TD(e)Tj6.2400 l100 TDom3000 0.9-0.1200(e)Tj6.2400 0.0000 TD(re)

[3] *See also* Appx. 637 (PX 126) (e-mail from Dr. Fujita to Andrew Lane stating that the claim of three times greater absorbability was an "unjustified extrapolation" of the rat study).

- a study of OSE (presumed to be the same type of calcium in AAACa) showing absorbability, but providing no comparative data;
- a study suggesting comparability between AAACa and milk calcium, but with inconclusive results; and
- a study indicating greater absorbability of OSE compared to calcium carbonate in fo

statistically significant difference between the impact on bone resorption of AAACa and calcium citrate." Appx. 599 (PX 55).

This is the body of research that defendants possessed when they promoted AdvaCAL as: the "only" calcium that can increase bone density; three (or four) times more absorbable than other calcium supplements; and comparable or superior to prescription drugs to treat osteoporosis. In their brief, defendants emphasize that their calcium expert, Dr. Holick, vouched for the validity of these studies and testified that they constituted "competent and reliable scientific evidence" as defined in the Final Orders. LL. Br. at 18-19, 21. But this begs the question: competent and reliable scientific evidence for what claims? In fact, Dr. Holick did not testify that defendants possessed competent and reliable scientific evidence to support their claims that AdvaCAL is the only calcium that can increase bone density, that AdvaCAL is three to four times more absorbable than other calcium, or that AdvaCAL is on par with prescription osteoporosis drugs.[4]

The district court simply disregarded these gaps in defendants' expert testimony, and instead focused exclusively on the testimony supporting defendants' general claims of efficacy. Contrary to defendants' contention, LL Br.

[4] As the Commission demonstrated in its opening brief ("FTC Br."), Dr. Holick testified, and Andrew Lane admitted, that defendants had no substantiation for yet another of their claims – that AdvaCAL had been clinically shown to increase one density in the hip. FTC Br. at 20-21.

at 10 & 16, the court's introductory statement that it considered the "complete record" and recitation, at the beginning of its Opinion, of the advertising claims challenged by the Commission does not demonstrate that the court assessed (much less "painstakingly assessed," *id.* at 12) the evidence regarding defendants' superiority claims challenged by the Commission. Significantly, nowhere else in its Opinion did the court discuss these critical issues. Although the court was certainly entitled to credit the testimony of defendants' experts, as defendants assert in their brief, it was not entitled to ignore the Commission's undisputed evidence showing that defendants lacked substantiation for the claim of AdvaCAL's purported superiority, in contravention of the Final Orders.

As discussed below, defendants have failed to demonstrate that the evidence concerning these superiority claims supported denial of the Commission's contempt motion.

B. The District Court Abused Its Discretion By Ignoring Undisputed Evidence That Defendants Lacked Substantiation For Their Claim That "Only" AdvaCAL Can Increase Bone Density.

Defendants imply that they did not make this claim after the effective date of the Final Orders. LL Br. at 23. This

When confronted with one of these ss1D

AdvaCAL. Appx. 382 (Tr. 1028) (agreeing that the data "is showing a change from base line that is higher"). Moreover, defendants were apparently aware of this study, because they included it in the "substantiation notebook" for AdvaCAL that they introduced at the hearing. Appx. 382 (Tr. 1029) (Andrew Lane acknowledged that defendants were aware of the study but stated, "I don't remember if I read it or not").

[6] *Compare* Dr. Holick's testimony that "anything above 1.00 means that there's an increase" in BMD above baseline value, Appx. 338 (Tr. 854-55), *with* Appx. 748 (Fig. 4 of PX 258) showing that non-fractured subjects receiving calcium carbonate showed increases in Beivei k"2

Moreover, at the same time that defendants seek to justify their claim of AdvaCAL's unique bone benefits on the ground that there are no comparable studies of other calcium products, they seek to excuse their lack of substantiation for the claim of "clinical studies" showing that AdvaCAL increases bone density in the hip on the ground that (because calcium is calcium) clinical studies of other calcium products showing bone density increases in the hip serve to substantiate claims about AdvaCAL as well. LL. Br. at 26.[7] Not only are these arguments mutually inconsistent, but also defendants' observation that other types of calcium have been found to increase bone density in the hip belies their claim that only AdvaCAL can increase bone density.

C. The District Court Abused Its Discretion By Ignoring Undisputed Evidence That Defendants Lacked Substantiation For Their Claim That AdvaCAL Is Three To Four Times More Absorbable Than Other Calcium.

Defendants implicitly concede that whatever support they may have for this claim relates only to calcium carbonate, not other calcium products. LL Br. at 27. Although calcium carbonate was certainly the "primary target" of this superiority claim, *id.*, defendants did not always limit their claim to calcium carbonate, but

---

[7] Defendants argue that their misrepresentations in claiming that they had "clinical studies" (when they had only animal studies) were "not a conscious plan" to violate the Final Orders, LL. Br. at 26; however, "willfulness is not a necessary element of contempt." *Harley-Davidson, Inc. v. Morris*, 19 F.3d 142, 148 (3rd Cir. 1994).

also broadly claimed, for example, that "AdvaCAL has been clinically shown to be three times more absorbable that other calciums" without limitation. *See, e.g.*,

absorb only about 20% of the calcium in a calcium carbonate subject (or approximately 4% if your stomach acid level is low), *it absorbs roughly four times as much of the specially processed calcium in AdvaCAL"*).[8]

But even if – counterfactually – defendants' had limited their claim of "three to four times greater absorbability" to the narrow context of calcium carbonate and individuals with achlorhydria, defendants lacked substantiation for this claim as well because, as both Andrew Lane and Dr. Holick conceded, AdvaCAL has never been studied in individuals with achlorhydria taking the product on an empty stomach (the conditions under which calcium carbonate has been shown to be poorly absorbed). Appx. 345, 386 (Tr. 881-82, 1046). For all defendants know, AdvaCAL might be poorly absorbed under those particular conditions as well.

This evidence compels a finding that defendants lacked "competent and reliable scientific evidence" for their claim that AdvaCAL is "three to four times more absorbable" than other calcium. Defendants' expert did not demonstrate otherwise. He merely testified that AdvaCAL "could be" better absorbed than calcium carbonate in individuals with achlorhydria, Appx. 341 (Tr. 866), not that

---

[8] Although this advertisement mentions the condition of achlorhydia (low stomach acid), it plainly indicates that absorbability of AdvaCAL is four times the 20% normal absorption value for calcium carbonate, implying that the comparative absorbablity of AdvaCAL is even greater than that in individuals with low stomach acid.

defendants' claim of "three to four times greater absorbablity" had actually been substantiated. Although defendants suggest that Dr. Holick's testimony likening certain formulations of calcium carbonate to chalk supports this claim of superior absorbability, LL. Br. at 27, in fact, Dr. Holick made it abundantly clear that chewable calcium carbonate supplements – such as antacid tablets (a product which defendants specifically referred to in making this superiority claim, *see* Appx. 852 (PX 537)) – are perfectly well absorbed, even in individuals with achlorhydria. Appx. 351 (Tr. 904, 907). Thus, Dr. Holick's testimony did not support defendants' superiority claim either.[9]

---

[9] The FTC will not repeat here the ample undisputed evidence demonstrating defendants' violations of Paragraph IV of the Final Orders (prohibiting misrepresentations of studies). *See* FTC Br. at 28-31. Two assertions in defendants' brief require a response, however. First, defendants mislead the Court in suggesting that Dr. Good (a statistician who did not testify at hearing) validated their inclusion of radial data in a chart purporting to depict spinal bone density results. LL. 32 &46. To the contrary, as defendants are perfectly well aware, Dr. Good specified at his deposition that it was improper for defendants to represent radial bone density data as spinal bone density data. *See* Appx. 3774 (Good Decl. ¶ 16) (stating that "*with one exception*" – the radial data – he thought the chart was appropriate). Furthermore, contrary to defendants' contention, LL. Br. at 33, no testimony (other than Andrew Lane's personal view) supported their inclusion of 6 month data in a chart purporting to show increases in BMD at 12 months. To the contrary, undisputed expert testimony established that it was improper for defendants to extrapolate 6 month data to 12 month data in this manner. Appx. 159 (Tr. 358).

lack of authorship notwithstanding), defendants' widespread dissemination of this newsletter containing unsubstantiated claims about AdvaCAL's equivalency (indeed, superiority) to prescription drugs violated the Final Orders.

Defendants also do not dispute that Andrew Lane himself made the unsubstantiated claim that AdvaCAL has been shown to have "bone building results on par with prescription pharmaceuticals." Appx. 897 (PX 589). Although defendants suggest that this claim does not constitute an order violation because it was made to a distributor in connection with pr

As the Supreme Court explained in *Guaranty Trust Co. of N.Y. v. United States*, 304 U.S. 126, 132 (1938), the rationale for this rule "is to be found in the great public policy of preserving the public rights . . . from injury and loss, by the negligence of public officers." *Accord United States v. Weintraub*, 613 F.2d 612, 618 (6th Cir. 1979). The courts have recognized that whatever concern there may be about "unfairness" to defendants engendered

[11] Defendants' argument that the cases cited by the FTC are irrelevant because they did not specifically involve compliance reports, LL Br. at 39, is patently without merit

Contrary to defendants' contention, LL Br. at 43, this Court's decision in *Harris v. City of Philadelphia*, 47 F.3d 1311 (3rd Cir. 1995), does not establish a more relaxed standard for a substantial compliance defense than that set forth in *Robin Woods*. Indeed, the Court in *Harris* did not address a substantial compliance defense at all, but instead addressed the entirely distinct defense raised by defendants that, di0 Tf TD(su)Tj15.8400 0.0000 TD(bs)Tj12.4800 0.0000.00000 0.0000 0.0000 cr

[12] Contrary to defendants' argument, LL. Br. at 20, the Court in *Harris* was on solid ground in placing the burden of establishing a defense on the defendants. *Harris v. City of Philadelphia*, 47 F.3d at 1324. *See Citronelle-Mobile Gathering, Inc. v. Watkins*, 943 F.2d 1297, 1301 (11th Cir. 1991) (burden is on party asserting the defense); *Food Lion, Inc. v. United Food & Commercial Workers, Int l Union*, 103 F.3d 1007, 1017 (D.C. Cir. 2008) (burden is on party asserting the defense).

that, though this defense may often be asserted, courts rarely rule in defendants' favor on this issue, and, when they do so, it is under circumstances entirely distinct than those present here. *See, e.g, Food Lion, Inc. v. United Food & Commercial Workers, Int l Union*, 103 F.3d 1007, 1017-19 (D.C. Cir. 2008) (rejecting defense, notwithstanding defendants' compliance efforts); *Halderman v. Penhurst State School & Hospital*, 154 F.R.D. 594, 608 (E.D. Pa. 1994) (rejecting defense, notwithstanding defendants' compliance efforts, because their violations of court order were "pervasive and profound"); *Raza v. Biase*, 2008 U.S. Dist. LEXIS 20526, at *12-13 (D.N.J. March 14, 2008) (reiterating that good faith is not a sufficient defense to contempt); *Bunzl Distribution Northeast, LLC v. Boren*, 2008 WL 43995, at *2 (D.N.J. Jan. 2, 2008) (reiterating that good faith is not a defense to contempt).

The fact that defendants hired a compliance officer and located research that substantiated *some* of their product claims, LL Br. at 45, does not suffice to insulate them from liability for making broad superiority claims that – as Dr. Heaney informed them from the outset – were not supported by that research. Although defendants protest that they did not simply ignore Dr. Heaney's warnings, but instead commissioned another study of AdvaCAL, the inescapable fact is that this other study did not substantiate defendants' superiority claims

either. *See* pp. 4-5, *supra*. Given these facts, the district court plainly erred in holding that defendants were entitled to a defense of substantial compliance.

IV. UNDISPUTED EVIDENCE ESTABLISHED THAT WILLIAM LANE VIOLATED THE FINAL ORDER ENTERED AGAINST HIM.

There is also no merit to William Lane's argument that his contumacious conduct should be excused. He does not seriously dispute that he was personally involved in the promotion of AdvaCAL, appearing in an infomercial and numerous of Lane Labs' print ads in which he made many of the claims that the FTC has challenged as unsubstantiated. He also does not dispute that he himself did little to ensure that the claims he was making about AdvaCAL were substantiated, as the Final Orders require, but instead left the matter of substantiation up to Lane Labs. *See* LL Br. at 9. Whether or not Dr. Lane was compensated for his promotional activities or exercised control over Lane Labs is irrelevant, because the Final Order was entered against him individually, not as a representative of Lane Labs.

Contrary to Dr. Lane's assertion, WL Br. at 22, the FTC has not simply "lumped" him in with the other defendants in this proceeding. It has not, for example, sought to hold him liable for order violations relating to Fertil Male. Nor has the FTC sought to hold him liable for the entire amount of the

the time period in which he appeared in the advertisements for AdvaCAL. *See* Dkt. 99 (FTC's Pre-Hearing Brief at 10, n. 9).

CONCLUSION

For the reasons stated above and those in its opening brief, the Commission requests that this court reverse the 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:

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

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

Dated: February 5, 2010

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 4,978 words, as counted by the WordPerfect word processing program.

3. Ser