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

REPLY BRIEF OF PLAINTIFF-APPELLANT FEDERAL TRADE COMMISSION

WILLARD K. TOM
General Counsel

JOHN F. DALY
Deputy General Counsel for Litigation

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

OF COUNSEL:

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

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ARGUMENT

Defendants' principal argument in this appeal is that the district court was entitled to find the testimony of defendants' experts to be more credible than that of the Commission's experts. Defendants would have this Court turn a blind eye (as did the district court) to the numerous instances in which their experts offered no opinion regarding whether a particular advertising claim was adequately substantiated or, in some instances, actually agreed with the Commission's experts. Defendants also ask this Court to overlook their own numerous admissions that they made broad superiority claims about AdvaCAL that were not substantiated by the studies of that product. This body of undisputed evidence clearly and convincingly establishes that defendants repeatedly violated their obligations under the Final Orders not to make unsubstantiated claims about their products, and belies any notion that they took all reasonable steps to comply with the Final Orders. The district court abused its discretion in holding otherwise.

I. THE DISTRICT COURT ERRED IN DENYING THE COMMISSION'S MOTION FOR CONTEMPT.

Contrary to defendants' contention, there has been no shift in the FTC's allegations against them over the course this contempt proceeding. *See* LL Br. at

3, 18.[1] From the beginning, the FTC has asserted that defendants violated the Final Orders by making unsubstantiated claims that: AdvaCAL is unique among calcium products in its ability to increase bone density, has been proven to be vastly superior to other calcium supplements, and, indeed, is comparable or superior to prescription osteoporosis drugs. Docket ("Dkt.") No. 10 (Memorandum in Support of FTC's Motion for Order to Show Cause); Dkt. No. 99 (FTC's Pre-Hearing Brief); Dkt. No. 113 (FTC's Post-Hearing Brief).[2]

A. The Substantiation Evidence On Which Defendants Rely Was Not Directed To The Challenged Claims.

The "large body of prior research" regarding AdvaCAL to which defendants refer, LL Br. at 6, may have demonstrated that product's efficacy as an absorbable

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[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 by the FTC, LL Br. at 8, such discovery was necessary because defendants failed to disclose information bearing on critical issues, including the extent of the claims made by them. For example, it was only as a result of subpoenas issued to third parties that the FTC discovered advertisements for AdvaCAL that appeared in widely circulated outside publications, which contained, among other things, the false and unsubstantiated claim that AdvaCAL is *four times* more absorbable than calcium carbonate. *See, e.g.*, Appx. 820 (PX 502). Moreover, defendants were continually revising their explanations about what substantiation supported their various advertising claims.

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 comparing two dosing regimes of AAACa, but making no comparison with other calcium sources;
- an animal study comparing AAACa with calcium carbonate (which Dr. Fujita himself testified did not support defendants' claims of AdvaCAL's superiority because, among other things, the method of calcium administration was "unphysiological," Appx. 715-16 (PX 206 at 262-62));[3]
- a poster presentation suggesting activity of the heated algal ingredient, but not sufficiently detailed for proper evaluation;

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[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 four subjects with hypocalcemia due to hypoparathyroidism.

Appx. 728-29 (PX 243). These studies provided "no convincing comparative data . . . that would support claims of superiority," Appx. 730 – and certainly not the particular claims of superiority that defendants made about AdvaCAL.

Because these studies did not support superiority claims that would give AdvaCAL a marketing edge over other calcium products (and allow defendants to charge correspondingly higher prices), *see id.*, Andrew Lane commissioned Dr. Heaney to conduct a study comparing AdvaCAL to calcium citrate in the hopes of obtaining substantiation for such claims. Unfortunately for defendants, this study did not demonstrate AdvaCAL's superiority, but instead showed that AdvaCAL was more poorly absorbed than calcium citrate. Appx. 731-42 (PX 244). Though defendants contend that a subsequent study they commissioned "confirmed the superior attributes of AdvaCal," LL Br. at 6, in fact, that study found "no

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 their claims 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 contention is demonstrably false. The evidence showed that defendants made this claim in their advertising throughout the relevant time period, including a 2002 direct mailing, Appx. 805 (PX 477)

("other calcium supplements cannot increase bone mass. AdvaCAL can."); a 2003 infomercial in which William Lane touted AdvaCAL's purportedly unique benefits, Appx. 836 (PX 537); and their 2006 promotional materials, Appx. 779 (PX 390) ("It's been nearly ten years and the other calciums still cannot build bone density.").

As discussed in the Commission's opening brief, this claim of a unique ability to build bone density is baseless because, 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. FTC Br. at 18-19. *See* LL Br. at 25 (conceding that "all calcium produces a bone benefit"). This claim of purported uniqueness rests on Andrew Lane's own say-so: he asserted that this claim was justified because AdvaCAL had been shown to increase bone mineral density ("BMD") above baseline value, whereas (he claimed) other types of calcium had not. Appx. 382 (Tr. 1029-30). The scientific evidence presented at the hearing, however, demonstrated otherwise. The Commission introduced studies showing that, contrary to Andrew Lane's contention, other types of calcium had been shown to increase BMD above baseline. Appx. 748 (PX 258, Table 4); Appx. 755 (PX 261, Figs. 1 & 2).[5] Dr. Heaney testified that these studies squarely

[5] When confronted with one of these studies, Andrew Lane was forced to concede that it showed an increase in BMD above baseline for calcium other than

contradict defendants' claim that AdvaCAL is the only type of calcium shown to build bone density. Appx 153 (Tr. 333-36). Although defendants now dispute the findings of these studies, LL Br. at 24, their expert did not: Dr. Holick did not offer any opinion concerning these studies, and did not dispute Dr. Heaney's testimony on this point.[6]

There is likewise no merit to defendants' contention that this claim of purported uniqueness is similar to another manufacturer's claim that its product, OsCal, is the only calcium proven to reduce hip fractures by 29%. LL. Br. at 25. Defendants' claim with regard to AdvaCAL was not even remotely so circumscribed. Rather, defendants claimed – categorically – that AdvaCAL is the only calcium that can increase bone density. *See* Appx. 779 (PX 390). Undisputed expert testimony, however, demonstrated otherwise.

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 BMD above 1.0 in femoral neck and lumbar spine).

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

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[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.*, Appx. 840 (PX 537). Defendants do not pretend to have "competent and reliable scientific evidence" to substantiate this general claim of superiority.

Even with regard to calcium carbonate, defendants do not purport in this appeal to have substantiation for their claim of "three to four times more absorbable" with regard to individuals who do not suffer from achlorhydria. Although defendants seek to excuse this lack of substantiation as to the general population by asserting that, in any event, their principal customers for AdvaCAL are elderly women who are more prone to achlorhydria, LL. Br. at 27-28, the evidence shows that defendants marketed AdvaCAL to adults of all ages. For example, defendants made the claim that AdvaCAL has been "Clinically Shown to be 3 Times More Absorbable," Appx. 840 (PX 537), in an infomercial directed at "men and women at all ages," including "as early as your thirties." Appx. 830-33. *See also* Appx. 850 (in infomercial William Lane touted AdvaCAL's vast superiority to the calcium carbonate in antacids as a source of calcium for pregnant women). The evidence also belies defendants' further contention, LL. Br. at 29, that their advertising expressly limited this claim to the context of achlorhydria. *See*, *e.g.*, Appx 840 (PX 537); Appx. 802 (PX 477) ("*where your system may*

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

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[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]

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[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).

D. The District Court Abused Its Discretion By Ignoring Undisputed Evidence That Defendants Lacked Substantiation For Their Claim That Advacal Is Comparable Or Superior To Prescription Osteoporosis Drugs.

Defendants do not dispute that they frequently included in their promotional materials for AdvaCAL a newsletter that proclaimed AdvaCAL's superiority to prescription osteoporosis drugs; that they referred to this newsletter as "our" report; and that they have no data to substantiate any comparison between AdvaCAL and prescription osteoporosis drugs. *See* FTC Br. at 25-28. Defendants insist, however, that because they did not author that newsletter themselves, their widespread dissemination of this claim in marketing AdvaCAL does not violate the Final Orders. LL. Br. at 30.[10] The Final Orders, however, specify otherwise: they expressly provides that defendants may use third-party literature in promoting their products only "when its use is not false, deceptive or misleading." Appx. 536, 555 (Para. VI). As Dr. Heaney testified, it is not true that calcium can substitute for prescription osteoporosis drugs. Appx. 160 (Tr. 361-62). Dr. Holick offered no opinion concerning this claim. This evidence establishes unequivocally that (their

[10] Contrary to defendants' assertion that the editor of this newsletter wrote it without any editorial direction from defendants, LL Br. at 30, the very document to which defendants cite shows that Andrew Lane began his correspondence with Ms. Reinagel by discussing at great length the shortcomings of prescription osteoporosis drugs, then touted AdvaCAL's performance, and concluded with the statement, "In several cases, [AdvaCAL] does a better job with BMD than the hormonal products." Appx. 892-96 (PX 588).

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 proposed sales outside the United States that "did not come to pass," LL Br. at 30, the Final Orders do not carve out an exception for claims made to distributors, claims made in connection with sales outside of the United States, or claims made in connection with unconsummated sales.

* * * *

Because the district court failed to consider this ample undisputed evidence demonstrating that defendants committed numerous significant violations of the Final Orders, the court erred in ruling that Commission failed to present clear and convincing evidence of contempt. Whether this error stemmed from the court's misapprehension of the nature of the advertising claims challenged by the Commission, its misunderstanding concerning the scope of the prohibitions in the

Final Orders, or other reasons, the conclusion is the same: the district court abused its discretion, and its order denying the Commission's contempt motion must be reversed. *See Roe v. Operation Rescue*, 54 F.3d 133, 137-40 (3rd Cir. 1995) (holding that the district court abused its discretion by "ignoring" undisputed evidence of order violations and "focus[ing] exclusively" on certain evidence, which "suggest[ed]" that the court applied an incorrect legal standard).

II. THE DISTRICT COURT ERRED AS A MATTER OF LAW IN HOLDING THAT THE COMMISSION'S FAILURE TO RESPOND SOONER TO DEFENDANTS' COMPLIANCE REPORTS JUSTIFIED DENYING THE CONTEMPT MOTION AS A MATTER OF "FUNDAMENTAL FAIRNESS."

There is no merit to defendants' contention that, because they never invoked the term "laches," and the district court disclaimed that it was applying a laches defense, it was appropriate for the court to hold that the Commission's delayed response to their compliance reports justified denying the contempt motion as a matter of "fundamental fairness." LL Br. at 37-38. Whether one calls it laches, neglect of duty, equitable estoppel, or "fundamental fairness," it is readily apparent that the district court applied the type of equitable defense that the Supreme Court and U.S. courts of appeals have uniformly held may not be asserted against the government in an action (such as this) enforcing a public right. *See* FTC Br. at 35-37 (discussing cases).

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 by governmental delay is overcome by the greater public interest in enforcement of the laws.

Moreover, this public policy would be undermined if government agencies were required to justify the timing of their law enforcement actions, as the district court demanded from the FTC. *See* Appx. 62 (Tr. 52). As the FTC's counsel noted, when pressed by the court on this subject, there are many factors that typically affect the timing of the FTC's actions, not the least of which is the competing demands for the agency's limited resources. Appx. 63 (Tr. 54-55). The FTC's unwillingness to provide a more particularized explanation than that was not "arrogant," as defendants' contend, LL Br. at 39, but the recognition that, as matter of public policy, such a justification is not required.

Notably, defendants have not cited (nor did the district court cite) any case law supporting the application of such a "fundamental fairness" defense to

contempt. That is not surprising, because, as the cases cited by the Commission establish, such a defense is not cognizable against the government.[11]

III. THE DISTRICT COURT ERRED AS A MATTER OF LAW IN HOLDING THAT DEFENDANTS ESTABLISHED A DEFENSE OF SUBSTANTIAL COMPLIANCE.

This Court has not clearly recognized substantial compliance as a defense to civil contempt, but has noted that other courts define the defense as follows: "If a violating party has taken all reasonable steps to comply with the order, technical or inadvertent violations of the order will not support a finding of civil contempt." *Robin Woods Inc. v. Woods*, 28 F.3d 396, 399 (3rd Cir. 1994) (internal quotation marks and citations omitted); *Chao v. Koresko*, 2005 WL 2521886, at *6 (3rd Cir. Oct. 12, 2005) (same). Applying this definition, this Court has rejected the defense where the violations in question were neither "technical" nor "inadvertent" and, in this context, has made clear that a contemnor's "good faith is not a defense to civil contempt." *Robin Woods Inc.*, 28 F.3d at 399; *Chao v. Koresko*, 2005 WL 2521886, at *6.

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[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. What these cases show is that the rule that laches (or whatever one calls the defense) may not be asserted against the government applies in all types of factual scenarios.

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, despite their good faith efforts, it was *impossible* for them to adhere to the terms of the order in question. *Id.* at 1321, 1324-25. (In contrast, defendants in this case have never argued that they were unable to comply with the Final Orders.) The Court affirmed the trial court's rejection of that defense, because defendants had failed to satisfy their burden of demonstrating an inability to comply with the order.[12] Significantly, the Court rejected the defendants' argument that they had acted in good faith, holding that defendants' "unilateral interpretation of the requirements for compliance" did not excuse their noncompliance. *Id*. at 1325. Thus, *Harris* does not help defendants here.

Nor do any of the other cases cited by defendants support the district court's application of the substantial compliance defense. To the contrary, the cases show

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[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 injury resulting from order violations concerning AdvaCAL, but only for injuries occurring during

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. Service upon counsel -- I hereby certify that, in addition to service accomplished by the CM/ECF system on February 5, 2010, a copy of the brief is being sent to 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 was detected. I used Symantec AntiVirus rev. 6 (updated to February 4, 2010).

s/ Michele Arington
MICHELE ARINGTON