PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

09-3909

FEDERAL TRADE COMMISSION,
Appellant

v.

LANE LABS-USA, INC; CARTILAGE
CONSULTANTS, INC.;
I. WILLIAM LANE; ANDREW J. LANE

On Appeal from the United States District Court
for the District of New Jersey
District Court No. 2-00-cv-03174
District Judge: The Honorable Dennis M. Cavanaugh

Argued September 14, 2010

Before: SLOVITER, BARRY, and SMITH,
Circuit Judges

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

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Theodora T. McCormick
Jack Wenik (argued)
Sills, Cummis & Gross
One Riverfront Plaza
Newark, NJ 07102
Counsel for Appellee Lane Labs-USA, Inc. and Andrew J. Lane

Paul F. Carvelli (argued)
McCusker, Anselmi, Rosen & Carvelli
210 Park Avenue
Suite 301
Florham Park, NJ 07932
Counsel for Appellee I. William Lane

Michele Arington (argued)
John F. Daly
Federal Trade Commission
Room H-582
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Elsie B. Kappler
Constance M. Vecellio
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Susan J. Steele
Office of United States Attorney
970 Broad Street
Room 700
Newark, NJ 07102

Amanda C. Basta
Kirkland & Ellis
655 15th Street, N.W.
Suite 1200
Washington, DC 20005
Counsel for Appellant

OPINION

SMITH, *Circuit Judge.*

The Federal Trade Commission ("FTC") appeals from an order of the United States District Court for the District of New Jersey denying its motion to hold Lane Labs-USA, Inc., I. William Lane, and Andrew J. Lane in contempt for violation of consent judgments entered by the District Court on July 6, 2000 and September 26, 2000. For the reasons set forth below, we conclude that the District Court committed clear error. Accordingly, we will

vacate the order of the District Court and remand for further proceedings.

I.

Lane Labs-USA, Inc. ("Lane Labs") is a manufacturing distributor of specialty dietary supplements and cosmetic products.[1] The company was founded in 1994 by its current president and sole shareholder, Andrew J. Lane ("Lane"). Lane's father, I. William Lane, is not an employee of Lane Labs, but has served as a consultant to the company since its founding.[2]

In June of 2000, the FTC charged the Lane defendants with deceptive acts in violation of § 5 of the Federal Trade Commission Act ("FTC Act").[3] The FTC's

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[1] Although Lane Labs is considered a "products manufacturer" under the Standard Industrial Classification Code, it outsources all manufacturing work for offsite production. The company's in-house staff is primarily concerned with distributing and marketing its products.

[2] For ease of reference, we collectively refer to Lane Labs, Andrew J. Lane, and I. William Lane as "the Lane defendants."

[3] Section 5 of the FTC Act prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1).

complaint focused upon unsubstantiated representations pertaining to two products: BeneFin, a dietary supplement, and SkinAnswer, a cosmetic cream.[4] Shortly after the litigation was commenced, however, each of the Lane defendants reached a settlement with the FTC and agreed to the terms of a consent decree. The District Court entered the decree as a stipulated final order for permanent injunction (hereinafter, the "Final Order"),[5] and adjudged Lane Labs liable for the sum of $1 million.

Two provisions of the Final Order are pertinent to

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[4] In a related action, the Food and Drug Administration ("FDA") filed a complaint against Lane Labs and Lane on December 10, 1999, alleging violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* Specifically, the government accused both defendants of misbranding and falsely advertising three products: BeneFin, SkinAnswer, and MGN-3. The United States District Court for the District of New Jersey agreed with the FDA, permanently enjoined the offensive conduct, and ordered payment of restitution to consumers who purchased these products. *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547 (D.N.J. 2004). We affirmed the District Court's decision the following year. *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219 (3d Cir. 2005).

[5] The District Court actually entered two stipulated final orders for permanent injunction, one against William Lane on July 6, 2000, and the other against Lane Labs and Lane on September 26, 2000. Both orders are identical in all material respects, except that monetary penalties were imposed against Lane Labs.

this appeal. In Section III, the Lane defendants agreed that "in connection with the manufacturing, labeling, advertising, promotion, offering for sale, or distribution of any food, dietary supplement, or drug," they would refrain from

> mak[ing] any representation, in any manner, . . . expressly or by implication, about the effect of [a] product on any disease or disorder, or the effect of such product on the structure or function of the human body, or about any other health benefits of such product, unless, at the time the representation is made, [they] possess[ed] and rel[ied] upon competent and reliable scientific evidence that substantiates the representation.

"Competent and reliable scientific evidence" was defined as "tests, analyses, research, studies, or other evidence based on the expertise 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." Section IV of the Final Order forbade express or implied misrepresentations regarding "the existence, contents, validity, results, conclusions, or interpretations of any test, study or research" in connection

with "the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, dietary supplement, or drug." Two other provisos, Sections IX and XIV, imposed record keeping and periodic reporting requirements, respectively.

Two products are at issue: AdvaCal, a calcium supplement, and Fertil Male, which, as the name suggests, purports to improve male fertility. We shall briefly consider the development and marketing of both products before turning to the proceedings that occasioned the instant appeal.

A. AdvaCal

AdvaCal was developed by a renowned Japanese scientist named Takuo Fujita. The product primarily consists of calcium hydroxide derived from oyster shells smelted at extremely high temperatures. Once the smelting process is complete, the calcium component is combined with a heated algae ingredient ("HAI") extracted from Hijiki seaweed. This combination of active ingredients purportedly yields a calcium hydroxide product that is significantly more absorbable by the human body than competing calcium supplements.

Lane Labs began marketing AdvaCal in 2000 as a means to increase bone strength and combat osteoporosis. Over the next several years, the company utilized an array of print, television, and online media to promote its product. Each of these advertisements contained numerous representations regarding AdvaCal's efficacy, and many compared AdvaCal to competing calcium supplements. Typical among the claims appearing in AdvaCal marketing materials were assertions that the supplement (1) was unique in its ability to increase bone mineral density, (2) was clinically proven to be more absorbable than other calcium supplements, and (3) was clinically shown to increase bone density in the hip. In addition, Lane Labs distributed literature promoting AdvaCal as comparable or superior to prescription osteoporosis medicine, and Lane told at least one prospective retail purchaser that the calcium supplement was "on par with" prescription pharmaceuticals.

Consistent with its obligations under the Final Order, Lane Labs provided the FTC with compliance reports pertaining to AdvaCal in 2001, 2004, and 2006. Each report attached print copies of AdvaCal-specific advertisements, as well as the scientific research upon which Lane Labs relied for its representations. The parties do not dispute that many of the marketing claims at issue

in this matter were disclosed to the FTC in the 2001 compliance report.

B. Fertil Male

Fertil Male is derived from a Peruvian plant known as "maca." After it is gelatinised and heated, the plant is combined with HAI. This combination allegedly enhances the human body's capacity to absorb maca, which purportedly improves male fertility parameters such as sperm production and sperm motility.[6] In October 2003, Lane Labs began marketing Fertil Male. One advertisement featured a customer who proclaimed that Fertil Male caused his sperm count to "skyrocket" within one month. Just as it had with AdvaCal, Lane Labs submitted an FTC compliance report disclosing its Fertil Male advertisements in 2006.

C. The Contempt Proceeding

On July 12, 2006, the FTC notified Lane Labs that

[6] The FTC's expert, Dr. Craig Niederberger, described sperm motility as "the wiggling of the sperm as if they were . . . going towards an egg."

certain Fertil Male advertisements contained misrepresentations which amounted to violations of the Final Order. One month later, the FTC provided Lane Labs with a similar notice concerning the marketing of AdvaCal. Both notices threatened litigation absent the negotiation of an appropriate settlement agreement. The parties did not reach a settlement. Thus, on January 12, 2007, the FTC filed a motion with the District Court to hold the Lane defendants in contempt for violating Sections III and IV of the Final Order. To remedy these purported violations, the FTC requested $24 million in monetary damages.

The District Court held a five-day evidentiary hearing on the motion beginning on April 20, 2009. Two expert witnesses testified on behalf of the FTC: Robert Heaney, a physician and researcher at Creighton University, offered testimony concerning AdvaCal, while Craig Niederberger, a urologist at the University of Illinois at Chicago, addressed matters pertaining to Fertil Male. The Lane defendants presented the testimony of two opposing experts. Boston University physician Michael Holick discussed Lane Labs' marketing of AdvaCal, and University of Massachusetts professor Machelle Seibel testified as an expert in reproductive medicine. Each of these witnesses discussed scientific studies relied upon by Lane Labs to support its marketing claims. The FTC

experts generally opined that the claims in question were not substantiated by competent or reliable scientific research; not surprisingly, experts for the Lane defendants contradicted this viewpoint.

In addition to these dueling experts, the Court heard testimony from, among others, Lane and Jennifer Morganti, a naturopathic doctor employed by Lane Labs from 2001 to 2004. Lane testified that he took the Final Order "extremely serious[ly]," and he spoke at length about the measures the company pursued to comply with the decree. Lane explained that: the Final Order was distributed to all senior management personnel; copies were sent to Lane Labs' customers; an outside company was retained to compile existing research and to monitor research updates; and Lane hired Morganti to serve as manager of nutritional research. Morganti testified that her primary responsibility was to scrutinize Lane Labs' marketing claims to ensure that each representation was supported by scientific research.[7] In all circumstances, however, the ultimate decision to utilize a particular claim was Lane's alone.

By order dated August 10, 2009, the District Court

[7] Lane also testified that marketing claims were vetted by Lane Labs' marketing department and its outside counsel.

denied the FTC's motion for contempt. The Court explained that it reached its decision after "carefully considering the complete record" and weighing the testimony of each party's witnesses. In the Court's view, "[a]ll four expert witnesses were credible and knowledgeable in their respective fields of expertise," but those testifying on behalf of the Lane defendants were more impressive "because their testimony and approach to the subject matter seemed more reasonable and in accordance with the [Final] Order[]." The Court also characterized Lane's testimony in a favorable fashion, stating that it "found Mr. Lane to be forthcoming and credible, and consider[ed] his testimony to be evidence of the efforts undertaken by Defendants to comply with the [Final Order]."

Against this backdrop, the Court ultimately found that the Lane defendants' marketing claims were supported by competent and reliable scientific evidence. Absent from the decision, however, was any detailed examination of the particular representations challenged by the FTC. Rather, the Court simply set forth, in a series of bullet points, a "representative selection" of the challenged assertions,[8]

[8] According to the District Court, the following claims comprised a "representative selection" of the AdvaCal-specific claims

eschewing an analysis of whether each claim found support in the record. It emphasized that AdvaCal was generally recognized as "a good source of calcium," and that there was little to no evidence that either AdvaCal or Fertil Male was ineffective or potentially dangerous. The Court went on to summarize the evidence as follows: "Lane Labs found a product and obtained scientific evidence that the product is efficacious. Lane Labs then consulted experts who opined that the research supporting the product and the product itself were good. Lane Labs acted in accordance with the spirit of the [the Final] Order[]." For the District Court, then, this matter was no more than a dispute over "good" products about which there was a

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challenged by the FTC: (1) AdvaCal has been "clinically shown to be three times more absorbable than other calciums"; (2) AdvaCal is "absorbed three times better than typical calcium carbonate/coral calcium supplements"; (3) AdvaCal is the "only" calcium that can increase bone mineral density; (4) AdvaCal produced a 3 percent per year increase in bone density "over a period of years"; (5) results from a "group" study demonstrate that AdvaCal caused a 13.5% increase in bone density over two years; (6) AdvaCal has been shown in clinical tests to increase bone density in the hip; and (7) a testimonial from a twenty-five-year-old woman who claimed that after taking AdvaCal, her bone density increased by 50% in six months. With respect to Fertil Male, the Court simply stated that "the FTC challenges Defendants' general claim that Fertil Male has been 'clinically-shown' to increase sperm production, sperm motility, and semen production."

"difference of opinion." The Court found the opinions proffered by the Lane defendants more persuasive and, consequently, determined that they had not disobeyed the Final Order.

The Court further concluded that even if the Lane defendants violated the Final Order, they were entitled to a defense of substantial compliance. According to the Court, the Lane defendants undertook "considerable effort[s] to comply with the [Final] Order[]," even if "the materials relied upon by Defendants are in hindsight not perfect." These efforts were frustrated by the FTC, which failed for several years to notify Lane Labs of potential Final Order violations. The Court explained that such governmental foot dragging "raise[s] a significant issue of fundamental fairness." In other words, the Lane defendants attempted to comply with the Final Order, believed in good faith that they were successful in doing so, and received no indication from the government that their efforts were misguided. Under these circumstances, the Court found that "Defendants took all reasonable steps to substantially comply with the [Final] Order[]." The motion for contempt was accordingly denied.

The FTC timely appealed.[9]

II.

We review the denial of a contempt motion for abuse of discretion. *See Marshak v. Treadwell*, 595 F.3d 478, 485 (3d Cir. 2009). "Reversal is appropriate 'only where the denial is based on an error of law or a finding of fact that is clearly erroneous.'" *Roe v. Operation Rescue*, 54 F.3d 133, 137 (3d Cir. 1995) (quoting *Harley-Davidson, Inc. v. Morris*, 19 F.3d 142, 145 (3d Cir. 1994)). A factual finding is clearly erroneous if it is "completely devoid of a credible evidentiary basis or bears no rational relationship to the supporting data." *Interfaith Cmty. Org. v. Honeywell Int'l, Inc.*, 399 F.3d 248, 254 (3d Cir. 2005) (internal quotations omitted); *see also Giles v. Kearney*, 571 F.3d 318, 322 (3d Cir. 2009) (explaining that "[c]lear error review is deferential" and that the district court's factual findings should be upheld when they are "plausible in light of the record viewed in its entirety" (internal quotations omitted)). Where factual findings are based upon the testimony of live witnesses, the deference due the district

[9] The District Court had subject matter jurisdiction pursuant to 15 U.S.C. § 45 and 28 U.S.C. § 1331. We have appellate jurisdiction under 28 U.S.C. § 1291.

court is even more considerable. *See Anderson v. Bessemer City*, 470 U.S. 564, 575 (1985); *United States v. Igbonwa*, 120 F.3d 437, 441 (3d Cir. 1997) (stating that "when the district court's decision is based on testimony that is coherent and plausible, not internally inconsistent and not contradicted by external evidence, there can almost never be a finding of clear error"). However, "a court may not insulate its findings from review by 'denominating them credibility determinations, [because] factors other than demeanor . . . go into the decision whether or not to believe a witness.'" *Giles*, 571 F.3d at 322 (alteration in original) (quoting *Anderson*, 470 U.S. at 575). With these principles in mind, we turn our attention to the contempt proceedings conducted by the District Court.

III.

Proof of contempt requires a movant to demonstrate "(1) that a valid order of the court existed; (2) that the defendants had knowledge of the order; and (3) that the defendants disobeyed the order." *Marshak*, 595 F.3d at 485 (internal quotations omitted); *Roe*, 919 F.2d at 871. These elements "must be proven by 'clear and convincing' evidence, and ambiguities must be resolved in favor of the party charged with contempt." *John T. v. Del. Cnty. Intermediate Unit*, 318 F.3d 545, 552 (3d Cir. 2003).

Although courts should hesitate to adjudge a defendant in contempt when "'there is ground to doubt the wrongfulness of the conduct,'" *Robin Woods Inc. v. Woods*, 28 F.3d 396, 399 (3d Cir. 1994) (quoting *Quinter v. Volkswagen of Am.*, 676 F.2d 969, 974 (3d Cir. 1982)), an alleged contemnor's behavior need not be willful in order to contravene the applicable decree, *John T.*, 318 F.3d at 552; *Harley-Davidson*, 19 F.3d at 148-49. In other words, "good faith is not a defense to civil contempt." *Robin Woods*, 28 F.3d at 399.

The first two elements of contempt are not in dispute. Both parties agree that the Final Order constitutes a valid court order and that the Lane defendants were well aware of its existence and prohibitions. Thus, it is only the final element of contempt—disobedience of a valid court order—about which the parties quarrel. The FTC argues that the Lane defendants disobeyed Sections III and IV of the Final Order, and that the District Court erred in holding otherwise. Section III requires that each of Lane Labs' marketing claims find substantiation in competent or reliable scientific research. According to the FTC, the District Court failed to consider the specific marketing claims challenged during the contempt proceeding. The FTC challenges four claims pertaining to AdvaCal:

A. Only AdvaCal can increase bone density.

B. AdvaCal has been shown in clinical tests to increase bone density in the hip.

C. AdvaCal is three to four times more absorbable than other calcium supplements.

D. AdvaCal is comparable or superior to prescription osteoporosis drugs.

The FTC also challenges the assertion that Fertil Male can cause sperm count to "skyrocket" in as little as one month. Finally, the government argues that it proved Lane Labs violated Section IV of the Final Order by distorting research regarding AdvaCal and other forms of calcium. We will address each of these contentions in turn.

A. Only AdvaCal Can Increase Bone Density

In various marketing fora, the Lane defendants claimed that AdvaCal was unique in its ability to increase bone density. One full-page print advertisement

proclaimed, "Clinical studies show that AdvaCal does what no other calcium does: actually increases bone density in women." A direct mail circular asserted, "Other calcium supplements cannot increase bone mass. AdvaCal can." Yet another print publication explains,

> When LaneLabs introduced AdvaCal and AdvaCal Ultra in the mid 1990s, the scientific view of calcium changed forever. Up until then, calcium supplements, at best, could only PREVENT bone loss. AdvaCal was different. AdvaCal demonstrated in multiple clinical studies that it could actually BUILD bone density quickly, naturally and safely.

In a 2003 infomercial, William Lane described AdvaCal as "the only calcium that I know of where you can actually increase bone density." Finally, on two occasions in 2005, Lane wrote to a book publisher to promote AdvaCal. In a February 9, 2005 email, Lane portrayed AdvaCal as "the one calcium clinically shown to build bone density in multiple human clinical studies. No other calcium can make that claim." Lane followed this electronic correspondence with a March 2005 letter stating, "AdvaCal offers the following benefits versus other calciums: Actually builds bone density. That's something no calcium

has demonstrated consistently in clinical research." Although each of these marketing claims were admitted into the record, none was substantively discussed in the District Court's order.

The FTC presented evidence demonstrating that these claims of uniqueness were unsupported by competent and reliable scientific research. According to its expert, Dr. Heaney, nearly all calcium supplements "produce a measurable increase in bone density." He characterized this effect of calcium intake as "common," and reinforced his opinion by pointing to his own research and the results of at least two other peer-reviewed calcium studies. Both studies showed increases in bone density when human subjects were provided with calcium supplements other than AdvaCal. Dr. Morganti, Lane Labs' former manager of nutritional research, bolstered Dr. Heaney's opinion, explaining that "there's a general consensus that calcium can build bone density." She also remarked, "[t]o say that no other calciums can build bone is probably not true."

The record is devoid of credible evidence to contradict the government's proffer. Dr. Holick did not even address AdvaCal's purported uniqueness, much less dispute Dr. Heaney's interpretation of research indicating that most calcium supplements increase bone density. In

fact, Lane was the sole witness who testified in defense of this claim, but his effort was without scientific support. Lane stated that clinical research on other forms of calcium had not produced results demonstrating an increase in bone density above baseline value; the peer-reviewed studies discussed and introduced into evidence by Dr. Heaney show otherwise. While Lane disputed the findings of these studies, his lay speculation does not constitute credible evidence sufficient to refute the expert testimony and evidence entered into the record through Dr. Heaney.[10]

On the basis of Lane's lay speculation, and in spite of expert testimony to the contrary, the District Court ruled that the Lane defendants "offered support and substantiation" for the claim that AdvaCal was unique in its ability to increase human bone density. The Court's finding is not plausible in view of the entire record. The Lane defendants were not merely asserting that AdvaCal

[10] Lane questioned the results of one study after "reading the abstract very quickly" on the stand. As a witness with no medical or scientific expertise, Lane was unequipped to credibly refute the government's expert after "quickly" skimming a research abstract during cross examination. What is more, the Lane defendants' own expert, Dr. Holick, undermined Lane's lay opinion, explaining that the analysis appearing in an abstract does not typically represent competent or reliable scientific evidence sufficient to support a given proposition.

produced beneficial bone-building results or outcomes that were superior to other calcium supplements; rather, the claims indicated that other supplements did not build bone at all. Dr. Heaney showed that such an assertion was untrue, and Dr. Holick offered no testimony to contradict him. We are thus left with the definite conviction that the District Court's finding is clearly erroneous and must be reversed.

B. AdvaCal Has Been Shown in Clinical Tests to Increase Bone Density in the Hip

The FTC moved into evidence two print documents—one a direct mailing, the other a two-page advertisement—in which Lane Labs touts clinical research exhibiting AdvaCal's ability to increase bone density in the hip. It is undisputed that no such clinical research exists,[11] a fact that the District Court did not address in its memorandum. In spite of this omission, our review of the record leaves us satisfied that the Court did not clearly err by finding that these representations were in accord with

[11] A clinical study is one performed upon human subjects. The studies relied upon by the Lane defendants, however, were animal studies.

Section III of the Final Order.

Dr. Holick pointed to two clinical studies supportive of Lane Labs' claims. Both appeared in peer-reviewed journals, and both showed that calcium increased bone density in the human hip. Although neither study administered AdvaCal to its subjects, Dr. Holick explained that the results were applicable to AdvaCal because "[o]nce the calcium is in your bloodstream, it doesn't make any difference what it was associated with before."[12] Thus, one could "extrapolate" the data generated in these generic calcium trials and apply the conclusions drawn therefrom to the likely effect of taking AdvaCal. In Dr. Holick's opinion, competent and reliable clinical research therefore showed that AdvaCal increases bone density in the human hip.[13] The District Court was entitled to rely upon this

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[12] We note that the logic of Dr. Holick's opinion serves to undermine Lane Labs' uniqueness claim, addressed *supra*.

[13] Although Dr. Heaney disagreed with Dr. Holick's ultimate opinion concerning these particular marketing claims, he did not dispute Dr. Holick's statement concerning the extent to which one could "extrapolate" data from one clinical trial and apply it to a similar product. For example, when Dr. Heaney was presented with one of the two reports cited by Dr. Holick in support of Lane Labs' claims, he testified as follows:

testimony, to credit Dr. Holick's reliance on data "extrapolated" from generic calcium studies, and to find that the Lane defendants did not violate the Final Order by making the claims in question. Accordingly, we will affirm the District Court's finding.

C. AdvaCal is Three to Four Times More Absorbable Than Other Calcium Supplements

In direct mailers, print advertisements, and in an infomercial, the Lane defendants represented that AdvaCal was three to four times more absorbable than other calcium supplements. One assertion characteristic of these claims appeared in a direct mail article distributed to Lane Labs' customers. In it, AdvaCal was described as "an extremely high-potency calcium supplement that is absorbed *four times better* than typical calcium-carbonate supplements."

Q: My question, Doctor, was, could one rely on this study for the proposition that AdvaCal reduces the risk of fracture in the hip?
A: One can—one can rely upon it for a statement that calcium reduces the risk of fracture at the hip.
Q: And therefore, AdvaCal does.
A: And therefore, presumably, AdvaCal does.

Dr. Heaney characterized such a contention as "not physically possible." He explained that the typical calcium carbonate supplement is absorbed at a rate of 30-35%; were AdvaCal capable of performing at the advertised rate, its absorption value would rise to 120%. Dr. Heaney testified that this is physiologically—and mathematically—unattainable. In fact, Dr. Heaney stated, "No adult that I've ever measured under any circumstance would ever have an absorption value above, say, 60 percent, and that's highly unusual."

The Lane defendants argue that AdvaCal was not marketed to the average individual, but rather to elderly females, a substantial number of whom suffer from conditions of achlorhydria and osteoporosis. Achlorhydric individuals cannot produce stomach acid and, as a result, absorb calcium at a rate significantly below average. In some patients, this rate is as low as 4%. Dr. Holick explained that it would not be unusual for an achlorhydric individual, whose calcium absorption rate is far below 30-35%, to absorb AdvaCal three to four times more effectively than calcium carbonate. In such circumstances, Dr. Heaney's criticism is inapplicable, for an achlorhydric patient may absorb AdvaCal three to four times more effectively and still not attain the average absorption rate of 30-35%.

The problem with this argument is its failure to account for the actual language of the challenged representations. Lane Labs' marketing did not include phraseology limiting its claims to elderly females suffering conditions of achlorhydria. A 2003 infomercial was typical: "Osteoporosis now strikes women and men of all ages, races and nationalities. But osteoporosis can be prevented. A key is taking the right calcium and the right calcium supplement is AdvaCal. . . . AdvaCal has been clinically shown to be three times more absorbable than other calciums."[14] Thus, although AdvaCal may in fact have been targeted at a particular population segment, the challenged representations do not, on their face, limit their

[14] The record contains several additional advertisements whose focus is not limited to elderly females suffering conditions of achlorhydria. For example, the Lane defendants' AdvaCal infomercial warned that an individual's long-term health would be impacted by "decisions that you make as early as your thirties." Another promotional document states in bold letters, "It's never too early to act," and describes AdvaCal as "an excellent supplement for women of all ages [and] . . . an excellent supplement for men." Yet another advertisement notes that "while most of us still think of osteoporosis as something that strikes women aged 60-plus, its precursor, osteopenia, is beginning to appear in women of 30 or even younger. And increasing numbers of men are also being diagnosed with this potentially debilitating condition. . . . [T]he good news is that there is a calcium supplement [AdvaCal] available right now that is clinically proven to fight osteoporosis."

claims to any particular target group.

The District Court did not address the incongruity between the Lane defendants' argument and the actual language of the marketing claims identified by the FTC. We consider this omission problematic, for the record contains some evidence that AdvaCal was, as a matter of fact, marketed toward individuals at risk of, or suffering from, achlorhydria. Lane testified that the company targeted "[o]lder women, [or] postmenopausal women," and much of its advertising generally appears to focus upon this segment of the population. In addition, Dr. Holick's testimony indicates that among this population segment, AdvaCal *could* be three to four times more absorbable than calcium carbonate. The District Court credited the testimony of both Lane and Dr. Holick, but it did not indicate whether AdvaCal was, as a matter of fact, marketed to elderly females at risk of, or suffering from, achlorhyrdria.

Clearly, AdvaCal does not produce ideal outcomes in every patient, but the question is whether Lane Labs' claims promised results that were unattainable for large segments of its audience. The District Court implicitly found that they did not. Were we sitting as the finder of fact, we likely would reach the opposite result. We are not,

of course, sitting as a court of first impression; rather, our role is to review the District Court's factual findings. Unfortunately, our attempt to do so is frustrated by the absence of a detailed discussion of whether Lane Labs over-promised on results that could not be attained. In fact, we are unable to say with certainty that the District Court implicitly addressed these claims because the opinion fails to discuss the AdvaCal target market, and gives no indication that the Court considered—and disposed of—this factual dispute. We therefore consider it appropriate to remand so that the District Court may address these particular claims more exhaustively.

D. AdvaCal is Comparable or Superior to Prescription Osteoporosis Medicine

In 1999, Lane sent a "pitch letter" to Monica Reinagel, who was then the editor of the Health Sciences Institute ("HSI") newsletter. In this correspondence, Lane lauded AdvaCal's potential, describing it as "a revolutionary calcium supplement . . . that has been clinically shown to actually build postmenopausal bone density, without the side effects of hormonal drugs or supplements." HSI published an article praising AdvaCal

shortly thereafter. The article proclaimed, *inter alia*, that AdvaCal "works as well or better than [leading prescription drugs], and without the substantial side effects and risks."

AdvaCal has never undergone scientific testing for comparison with any prescription drug, and Dr. Heaney opined that the above-described claim of comparability/superiority was without competent or reliable substantiation. Notably, the Lane defendants made no attempt to dispute Dr. Heaney's opinion, and our review of the record has revealed no evidence supportive of this particular marketing claim. However, the Lane defendants argued before the District Court that the representation was not their own, and that they had no control over the content appearing in HSI's newsletter. This assertion was, quite simply, more than a stretch. And, surprisingly, the Lane defendants persist in pressing the argument on appeal. Lane himself acknowledged that Lane Labs paid for the right to distribute the article, and then did so "extensively." It was distributed to past and current customers in direct mailing packets and featured in retail store displays. In short, the Lane defendants adopted HSI's characterization by aggressively promoting the newsletter's content.[15] They

[15] The Final Order requires that the use of third party publications in advertising and promotion not be "false, deceptive, or

cannot run from the representation now that its veracity has been subjected to the spotlight.

The District Court did not address Lane Labs' comparability/superiority claim or its use of the HSI article to promote AdvaCal. It is therefore unclear whether the Court found substantiation for the claim or whether it accepted Lane Labs' attempt to absolve itself from propagating the representation. In either event, the District Court's finding was clearly erroneous; there is no dispute that the comparability/superiority claim was unsupported by competent or reliable scientific evidence and, by their own admission, the Lane defendants used this claim to market AdvaCal. Thus, this claim violates Section III of the Final Order and the District Court's holding to the contrary is clear error.

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misleading" under § 5 of the FTC Act, and precludes the Lane defendants from disseminating to "any distributor any material containing any representation prohibited by [the Final] Order." During cross examination, Lane acknowledged that the HSI article constituted a third party publication.

E. Fertil Male Can Cause Sperm Count to "Skyrocket" in as Little as One Month

Lane Labs published an advertisement for Fertil Male which claims, *inter alia*, that the supplement caused a male customer's sperm count to "skyrocket" after one month's use. This is the sole Fertil Male representation challenged by the FTC on appeal. Although the District Court did not discuss this specific representation, it expressly credited the testimony of Dr. Seibel, who stated that there was competent or reliable scientific evidence suggesting that Fertil Male improves male fertility parameters such as sperm count, sperm motility, and sperm production.

The FTC attempts to overcome Dr. Seibel's testimony by focusing on the one-month time span identified in Lane Labs' advertisement. According to the FTC, it is impossible for a fertility supplement to increase sperm count in such a short time. The government did not challenge this specific aspect of the Fertil Male claim during the contempt hearing, however, and thus there is little testimony which addresses the contention directly. Dr. Seibel explained that the process of spermatogenesis

requires at least three months,[16] but he did not explicate the precise manner in which spermatogenesis is related to changes in sperm count. Moreover, when the FTC confronted Dr. Seibel with the print advertisement in question, the following exchange transpired:

> Q: Let's look at the next paragraph: "The results were dramatic. In the first month Joe's sperm count skyrocketed."
>
> Now, Doctor, in a month, Fertil Male could not have caused the sperm count to skyrocket because the sperm wouldn't have been created yet[?] . . .
>
> A: Well, the entire impact would require a longer time.
>
> Q: But particularly, sperm count, you told us that sperm takes three months to go from inception to emission; correct?
>
> A: To see an absolute effect, yes.

[16] Dr. Seibel defined spermatogenesis as "the evolution of the sperm into a mature sperm."

The Court then attempted to clarify whether it was possible for male sperm count to increase over the course of one month's time.

> THE COURT: Could a male's sperm count increase in the first month, or is that something that just couldn't happen?
>
> THE WITNESS: It could have happened as part of the regression to the mean. It could have happened because the sperm—the maca had some effect inside the testes in a way I don't understand.
>
> But in general, it's a—it's a three-month window.

Neither party pursued this line of questioning any further after this exchange.

Dr. Seibel testified unequivocally that there was competent or reliable scientific research to substantiate the claim that Fertil Male increased sperm count. In the

excerpt above, he indicates that the "absolute effect" of an increase requires a period of three months, but appears to imply that some positive change also occurs within the first month. The FTC declined to delve further into this inquiry when it had the opportunity, but now asks that we set aside the District Court's factual findings on the basis of testimony that is ambiguous at best. We decline this invitation. The finding of the District Court with respect to this marketing claim will stand.

F. Distortion of Research

According to the FTC, the District Court committed error by finding that Lane Labs did not violate Section IV of the Final Order. Section IV forbids express or implied misrepresentations regarding "the existence, contents, validity, results, conclusions, or interpretations of any test, study or research" pertaining to "the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, dietary supplement, or drug." The District Court's Section IV analysis is brief. It began by acknowledging that "some of the statements contained in the advertising claims made by [the Lane defendants] were incorrect," and that "errors were made over a number of years." These misstatements and errors are nowhere identified. Instead, the Court focused upon AdvaCal's

general efficacy, noting that the supplement was considered to be "a good source of calcium" and "will most likely help the people who take [it]." The Court then concluded that the evidence was insufficient to show that the representations in question created a "false impression" in violation of Section IV.

The District Court's analysis is problematic. Section IV of the Final Order prohibits the Lane defendants from misrepresenting the results of research and data; it is simply unconcerned with a product's overall salutary effects. That AdvaCal is efficacious in delivering calcium to the body does not, *ipso facto*, preclude the Lane defendants from misrepresenting scientific research. Nor did the District Court's characterization of AdvaCal as a "good product[]" relieve it of the duty to make particularized findings of fact germane to the purported misrepresentations challenged by the FTC. Rather, it was incumbent upon the Court to examine the alleged misrepresentations in detail and to explicitly find whether each transgressed the proscriptions of Section IV.

The District Court's failure to provide us with a reasoned basis for concluding that Lane Labs did not violate Section IV prevents us from exercising meaningful review. Many of the challenged representations appear

misleading on their face, and the District Court provides no rationale for its conclusion that they are not. For example, a direct mailing advertisement asserted, "In clinical tests [AdvaCal] has been shown to actually increase bone density—even in the critical hip bones . . . ." It was not disputed, however, that the Lane defendants lacked such clinical research. Even Lane conceded, "There are no clinical studies on AdvaCal in the hip. . . . [W]e can't verify that statement." Without any explanation from the District Court, we are unable to determine if this claim was even considered in its Section IV analysis. And, if it was, it is difficult to comprehend how the representation did not "create[] a false impression in violation of Section IV."

Other challenged representations appear equally misleading. Rather than speculate as to the factual basis underlying the District Court's ultimate conclusions, we will return this matter to the District Court so that it may make findings that are more specific than those presently before us. Some of the representations are unlikely to survive careful factual scrutiny, but we leave the initial resolution of each issue to the District Court. The findings pertaining to the Lane defendants' alleged violation of Section IV will therefore be vacated.

IV.

The District Court held that even if the Lane defendants violated Sections III and IV of the Final Order, they were entitled to a defense of substantial compliance. We have never explicitly recognized the validity of the substantial compliance defense, *see Robin Woods*, 28 F.3d at 399, but we note that several of our sister circuits have done so, *see Morales-Feliciano v. Parole Bd. of P.R.*, 887 F.2d 1, 4-5 (1st Cir. 1989); *Gen. Signal Corp. v. Donallco, Inc.*, 787 F.2d 1376, 1379 (9th Cir. 1986); *see also Food Lion, Inc. v. United Food & Commercial Workers Int'l Union, AFL-CIO-CLC*, 103 F.3d 1007, 1017 (D.C. Cir. 1997) (assuming substantial compliance defense "survives" in the D.C. Circuit). Neither party has objected to the District Court's application of the defense, and, in fact, both appear to proceed under the assumption that the defense is cognizable under this Court's jurisprudence.

In *Robin Woods*, we favorably referenced a decision of the Court of Appeals for the Ninth Circuit and set forth the two-part substantial compliance defense adopted therein. The rule permits a party cited for contempt to assert the defense if it (1) has taken all reasonable steps to comply with the court order at issue, and (2) has violated the order in a manner that is merely "'technical'" or

"'inadvertent.'" *See* 28 F.3d at 399 (quoting *Gen. Signal Corp.*, 787 F.2d at 1379). Other courts apply a variation on this rule. The District of Columbia Circuit has stated the defense this way: "In order to prove good faith substantial compliance, a party must demonstrate that it 'took all reasonable steps within [its] power to comply with the court's order.'" *Food Lion*, 103 F.3d at 1017 (quoting *Glover v. Johnson*, 934 F.2d 703, 708 (6th Cir. 1991)); *see also Salazar v. District of Columbia*, 602 F.3d 431, 441 (D.C. Cir. 2010) (same). In the First Circuit, the rule is even less definitive: "substantiality," like reasonableness, "depend[s] on the circumstances of each case, including the nature of the interest at stake and the degree to which noncompliance affects that interest." *Fortin v. Comm'r of Mass. Dep't of Pub. Welfare*, 692 F.2d 790, 795 (1st Cir. 1982).

The Lane defendants cite to our decision in *Harris v. City of Philadelphia*, 47 F.3d 1311 (3d Cir. 1995), and urge us to adopt a substantial compliance test akin to that which is applied in the District of Columbia Circuit. In other words, they argue that "'a defendant may not be held in contempt as long as it took all reasonable steps to comply.'" Appellee's Br. at 42 (quoting *Harris*, 47 F.3d at 1324). In *Harris*, we were concerned not with substantial compliance, but the defense of impossibility. The City of

Philadelphia was under court order to improve conditions in its prisons; it failed to fulfill the terms of the order and contempt sanctions were pursued. On appeal, we recognized that "the City would have a valid defense were it able to show physical impossibility" to comply with the court order. *Id.* at 1324. We then cited authority recognizing the impossibility defense and holding that such a position is available only to those defendants that show they have made "in good faith all reasonable efforts to comply." *Id.* (internal quotations omitted).

The impossibility defense necessarily requires the defending party to assert a present inability to comply with the relevant court order. *See Hicks v. Feiock*, 485 U.S. 624, 638 n.9 (1988); *United States v. Rylander*, 460 U.S. 752, 757 (1983). It "refers to physical impossibility beyond the control of the alleged contemnor."[17] *Inmates of Allegheny County v. Wecht*, 874 F.2d 147, 152 (3d Cir. 1989) (citing *United States v. Bryan*, 339 U.S. 323, 330-31 (1950)), *vacated on other grounds*, 493 U.S. 948 (1989). Such an assertion will naturally precipitate judicial inquiry

[17] An alleged contemnor may also argue that a change in the law has rendered compliance illegal, even if it is physically possible. *See, e.g.*, *Halderman v. Pennhurst State Sch. & Hosp.*, 673 F.2d 628, 638-39 (3d Cir. 1981). This defense is not implicated in the present matter.

into the feasibility of the defendant's compliance. *See, e.g.*, *Spallone v. United States*, 487 U.S. 1251, 1256, 1258 (1988) (rejecting impossibility defense when city had not attempted certain extreme measures to obtain city council compliance with court order); *Harris*, 47 F.3d at 1340-42 (rejecting impossibility defense when city underfunded and understaffed court-ordered rehabilitation center, thereby leading to its failure to comport with required standards); *Wecht*, 874 F.2d at 152 (rejecting impossibility defense when government officials took insufficient steps to enable prison warden to comply with court order). Thus, a tribunal that concludes that contempt is excused on grounds of impossibility is essentially declaring that the defendant was incapable of compliance in spite of his or her best efforts. Substantial compliance evokes a standard somewhat less demanding. A party substantially complies when it takes all reasonable steps to do so, but nonetheless contravenes the court order by good faith mistake or excusable oversight.[18] The distinction is important, for a

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[18] According to the FTC, the Lane defendants' good faith efforts to comply with the Final Order are irrelevant and should have no bearing on the substantial compliance inquiry. This argument is based upon a misreading of our jurisprudence. As we explained in *Robin Woods*, an alleged contemnor may not invoke its good faith efforts as a *defense on the elements* of civil contempt. *See Robin Woods*, 28 F.3d at 399 (stating that "willfulness is not a necessary

party that substantially complies is physically capable of doing so; it has simply erred in a manner for which it would be inequitable to impose contempt sanctions.

Recognizing that we did not formally adopt the defense of substantial compliance in *Robin Woods*, we do so here. In order to avail oneself of the defense, a party must show that it (1) has taken all reasonable steps to comply with the valid court order, and (2) has violated the order in a manner that is merely "technical" or "inadvertent." The District Court's application of the appropriate test for substantial compliance is a legal issue to be reviewed de novo. *See Anderson v. City of Phila.*, 845 F.2d 1216, 1220 (3d Cir. 1988). Whether the alleged contemnors took all reasonable steps to comply with the

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element of civil contempt," and that "good faith does not bar the conclusion . . . that [the defendant] acted in contempt" (alterations in original) (internal quotations omitted)). When assessing the *affirmative defense* of substantial compliance, however, good faith efforts inherently factor into the inquiry. *See id.* (considering contemnor's good faith efforts but nevertheless concluding that violations were neither technical nor inadvertent); *see also Food Lion*, 103 F.3d at 1017 (explaining that good faith is relevant when assessing substantial compliance). Indeed, an "inadvertent" error is one that is, by its very nature, made in good faith. This is not to say that a party's good faith efforts necessarily convert its contumacious conduct into inadvertent violations; rather, good faith is relevant to the substantial compliance inquiry, no more, no less.

court order, and the extent to which contumacious conduct constitutes a "technical" or "inadvertent" violation, are factual questions subject to review for clear error. Resolution of these questions will naturally depend upon the unique facts of each case, the nature of the conduct precluded, and the capabilities of the parties subject to the order.

In the instant matter, the District Court set forth the correct standard for substantial compliance, explaining that "[i]f a respondent has made in good faith all reasonable efforts to comply with a court order, technical or inadvertent violations of the order will not support a finding of contempt." The Court then applied this rule to the facts, emphasizing the Lane defendants' considerable efforts to comply with the Final Order. In particular, the Lane defendants submitted timely compliance reports disclosing the representations in question; the FTC did not respond to these disclosures and, as the Court explained, "to tell Defendants that their efforts were not good enough years after not advising them of any compliance issues is disingenuous and is highly relevant to the inquiry into whether Defendants should have done something different in the first instance." The Court concluded by recognizing "that the materials relied upon by Defendants are in hindsight not perfect," but that "Defendants took all

reasonable steps to substantially comply with the [Final Order]." It did not explicitly address the extent to which violations of the Final Order were "technical" or "inadvertent."

The FTC assails this omission, arguing that the District Court's opinion contains no findings addressing the second step of the substantial compliance inquiry. We are hard-pressed to disagree. The entirety of the Court's substantial compliance analysis is focused upon the reasonableness of the Lane defendants' actions. The Court underscores Lane Labs' submission of compliance reports; its retention of additional compliance personnel; and the government's delay in commencing an enforcement proceeding.[19] Each of these considerations inherently

[19] The FTC mistakenly accuses the District Court of applying a laches defense in favor of the Lane defendants. Although the laches defense was briefed by the parties before the District Court, that Court correctly characterized it as a "mis-conceptualiz[ation]" of the issue. We are satisfied that the Court considered the FTC's prolonged delay in initiating contempt proceedings only insofar as it reflected upon the reasonableness of the Lane defendants' conduct. Such consideration is eminently appropriate. In fact, we share the District Court's concerns. In 2007, the FTC accused the Lane defendants of numerous misrepresentations, many of which were disclosed in compliance reports as early as 2001. After providing the government with its advertising and the research relevant thereto, the Lane defendants heard nothing for a period of years. To construe the

impacts the reasonableness inquiry, but does little to illuminate the justification for violating the Final Order. Moreover, although the Court implicitly recognized that some violations occurred, it neither identified this misconduct nor explained why the conduct qualified as a "technical" or "inadvertent" violation of the Final Order. Absent specific findings addressing this second step of the substantial compliance test, we are reduced to guesswork: speculating at that which the District Court considered contumacious conduct; speculating whether it found that such conduct technically violated the court order, or did so inadvertently; and speculating whether the District Court overlooked this necessary second step and neglected to consider the nature of the violations at all. In short, we are unable to conduct meaningful appellate review.

Accordingly, we will vacate the District Court's finding that the Lane defendants substantially complied with the Final Order, and will remand for reconsideration consistent with the discussion set forth above.

FTC's silence as approval was technically mistaken, but it was not unreasonable. We are, of course, sympathetic to the FTC's significant regulatory and enforcement responsibilities, but delays of this extraordinary length are inordinate. In sum, it was proper for the District Court to consider these facts in its reasonableness assessment.

V.

The District Court examined the record in its entirety and concluded that the Lane defendants complied with "the spirit" of the Final Order. This was insufficient. The District Court was not petitioned for an assessment of the general efficacy of AdvaCal and Fertil Male. Rather, the FTC contended that specific marketing claims were violations of two previously-entered consent decrees. Unfortunately, the able District Judge did not provide sufficiently detailed findings or sufficient rationale to allow us to perform effective appellate review. For the reasons set forth above, we will remand this matter to the District Court for further proceedings consistent with this opinion.