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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

FEDERAL TRADE COMMISSION,  
Plaintiff,

v.

LANE LABS-USA, INC., CARTILAGE  
CONSULTANTS, INC., corporations, and  
I. WILLIAM LANE and ANDREW J. LANE,  
individuals,

Defendants.

Hon. Dennis M. Cavanaugh

00CV3174 (DMC)

**MEMORANDUM OF PLAINTIFF  
FEDERAL TRADE COMMISSION IN  
SUPPORT OF MOTION FOR ORDER TO  
SHOW CAUSE WHY DEFENDANTS  
SHOULD NOT BE HELD IN CONTEMPT**

**RETURN DATE: FEBRUARY 12, 2007**

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In 2000, the Federal Trade Commission (“FTC”) entered into Stipulated Final Orders<sup>1</sup> with the Defendants in connection with their marketing and sale of two products: SkinAnswer and BeneFin. Each order required the Defendants to have competent and reliable scientific evidence to substantiate any representation they made regarding the effect of any product on any disease or disorder or the structure or function of the human body, or about any other health benefits of such product. (Tabs A and B ¶ III.) The orders also barred the Defendants from misrepresenting the results of any tests, studies or research. (Tabs A and B ¶ IV.) The FTC is now compelled, once again, to take action against the Defendants based on spurious and contemptuous claims made in their advertising of two other products, Fertil Male and AdvaCAL. Accordingly, the FTC brings this Motion for Order to Show Cause Why Defendants Should not be Held in Contempt.

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<sup>1</sup> On June 30, 2000, the parties jointly submitted two Stipulated Final Orders to this Court (Bassler, J.), one pertaining to Lane Labs-USA, Inc. (“Lane Labs”) and Andrew Lane, and the other pertaining to Cartilage Consultants, Inc. and I. William Lane (“William Lane”). On July 6, 2000, this Court (Bassler, J.), entered the Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief as to the latter Defendants only. After resubmission by the parties on September 26, 2000, this Court, on September 28, 2000, entered the Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief as to Lane Labs and Andrew Lane.

Since at least 2003, Defendants Lane Labs and Andrew Lane<sup>2</sup> have been marketing and selling Fertil Male. Lane Labs has expressly and impliedly represented through its labeling and advertising that this product improves male fertility. It has done so, however, based on irrelevant and flawed scientific studies, and accordingly, has failed to substantiate its claims. Lane Labs' claims about the efficacy of Fertil Male likewise distort and misrepresent the results of tests and studies on this product, in violation of the Order.

Defendants Lane Labs and Andrew Lane have marketed and sold AdvaCAL since 2000. Lane Labs also makes numerous unsubstantiated claims about the benefits of this calcium product and, in doing so, has misrepresented the results and conclusions of tests and studies. The conclusions of these studies do not support the Defendants' claims, and, in any event, the studies themselves are fatally flawed. William Lane has been complicit in making these claims – actively promoting this product through appearances as an expert endorser in print advertisements and infomercials – and accordingly, has violated the Order separately entered against him.

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<sup>2</sup> Andrew Lane, President and sole shareholder of Lane Labs, is actively involved in the advertising and marketing of Lane Labs' products.

The Defendants' unsubstantiated claims constitute contempt and have resulted in injury to consumers. Compensation to these consumers is necessary in order to remedy the Defendants' contempt. Therefore, the FTC asks that this Court grant its Motion for Order to Show Cause Why Defendants Should not be Held in Contempt, and other appropriate relief.

## **I. Procedural History and Injunctions**

On June 27, 2000, the FTC filed an action in this Court against Cartilage Consultants, Inc., William Lane, Lane Labs and Andrew Lane. The FTC's allegations against these Defendants involved two products marketed and sold by Defendants: BeneFin and SkinAnswer. The FTC charged the Defendants with making unsubstantiated claims about the efficacy of these products in treating cancer; false representations regarding the clinical proof of the efficacy of these products; and false representations regarding the Food and Drug Administration's evaluation of BeneFin.<sup>3</sup> The FTC's prayer for relief sought an injunction against

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<sup>3</sup> In December 1999, the Food and Drug Administration sued Lane Labs for promoting BeneFin (shark cartilage), Skin Answer (skin cream), and another product, MGN-3 (rice bran/shiitake mushroom), as drugs without requisite new drug FDA approval. In July 2004, the district court issued a permanent injunction against future sales of the products "or any drug that is a 'new drug' until a new drug application was approved for them," and ordered restitution. Lane Labs appealed the District Court's authority to grant restitution under the Federal Food, Drug and Cosmetic Act. On October 21, 2005, the Third Circuit affirmed the district court's order of restitution. U.S. v. Lane Labs-USA, 2005

unsubstantiated claims for the two products, misrepresentation of test results; refund of monies paid by purchasers of the products, and disgorgement. The Defendants settled these claims, and settlement led to the entry of the Orders referenced above. The Defendants have acknowledged receipt of the Orders. (Tab C Exhs. 1 and 2.)<sup>4</sup>

## **II. The Products and Claims at Issue**

### **A. Fertil Male**

Since 2003, Lane Labs has marketed Fertil Male as a “natural supplement for male fertility.” The product contains LMG, a Peruvian plant root also known as maca or *Lepidium meyenii*. (Tab C ¶ 39.) A one-month supply of Fertil Male costs \$39.95 at retail. (Tab C Exh. 28.)

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U.S. App. LEXIS 22734. Lane Labs subsequently settled this matter for \$8 million.

<sup>4</sup> Under the Orders, the Defendants were, within sixty (60) days after entry of the Orders, and “at such other times as the Commission [might] reasonably require,” to file reports with the Commission demonstrating their compliance with the Order. At the FTC’s request, the Defendants submitted compliance reports in 2001, 2004, and 2006. (Tab C ¶ 2.) Included in the 2001, 2004 and 2006 reports, among other things, were copies of Lane Labs’ advertising for AdvaCAL. Included in the 2004 and 2006 compliance reports were copies of Lane Labs’ advertising for Fertil Male. (Tab C ¶ 2.) Also included in these compliance reports were studies and other research on which the Defendants rely in support of their claims for these products. (Tab C ¶ 2.)

Advertising and promotional claims for Fertil Male appear in four sources: (1) the product label; (2) CompassioNet catalogs from 2003-2006; (3) the current CompassioNet website; and (4) the current Lane Labs website. (Tab C ¶ 3 Exhs. 26-31.)

The Defendants, on the label for the product, state that “Fertil Male is clinically shown to promote sperm count and motility.” (Tab C Exh. 27.)

Lane Labs and/or CompassioNet websites and CompassioNet catalogs are replete with bold claims that Fertil Male will enhance a man’s fertility. For example:<sup>5</sup>

“Fertil Male is clinically shown to promote sperm count, sperm motility (movement) and semen production without changing hormone levels. It has LMG, a Peruvian plant root infused with HAI, a patented amino acid complex that dramatically enhances absorption. In one human research study, benefits were noted in four months.” (Tab C Exh. 27.)

[Testimonial] “LMG is an important ingredient that helps promote male fertility. Most of its attributed properties have been corroborated scientifically.” (Tab C Exh. 27.)

“HUSBAND + WIFE + FERTIL MALE = ONE BIG HAPPY FAMILY!  
Kelli and Joe Faber ... love being parents. It took them 2 years and a lot of trying to have Cassandra (now 4). So when they started thinking about having another baby, Kelli suggested something different. A Lane Labs employee, Kelli had read the research on Fertil Male. ... Kelli brought some home for Joe to try. The results were dramatic. In the first month, Joe’s sperm count skyrocketed. And less than a year later, baby Madeline made

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<sup>5</sup> See also Tab C Exhs. 28 and 29.

her appearance. ‘We didn’t do anything special,’ Kelli marvels. ‘It just happened.’” (Tab C Exhs. 30 and 32.)

As the discussion below demonstrates, Lane Labs’ explicit and implicit claims that Fertil Male boosts fertility are unsubstantiated by competent and reliable scientific evidence, and misrepresent the results of tests and studies involving *Lepidium meyenii*.

## **B. AdvaCAL**

AdvaCAL, or AAACa, is an oyster-shell derivative. The shells (calcium carbonate) are super-heated, yielding calcium hydroxide and calcium oxide. This product is then combined with specially processed algae (“heated algae ingredient” or “HAI”), which Defendants claim enhances the absorbability of the calcium.

Lane Labs began marketing AdvaCAL in 2000. It advertises this product on its websites ([www.lanelabs.com](http://www.lanelabs.com) and [www.compassionet.com](http://www.compassionet.com)), the CompassioNet catalog, by direct mail, and on infomercials. (Tab C ¶ 3, 7, 19 Exhs. 1, 4-7, 8, 10-13.) During the period at issue in this case (2000 through the present), a 25 day supply of AdvaCAL (150 pills)<sup>6</sup> sold for \$39.95 at retail, which is many times the price of comparable calcium products. (Tab C ¶ 8 Exh.10.) As the discussion

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<sup>6</sup> Daily dose of 900 mg, 90% daily value.

below shows, Defendants have charged a premium for AdvaCAL based on unsupported and likely false representations of superiority.

Lane Labs' claims can be divided broadly into three categories. First, Lane Labs claims that AdvaCAL can "build bone" or increase bone mineral density where and to an extent other calcium and prescription products cannot. (Tab C Exhs. 4-13.) Second, Lane Labs claims that AdvaCAL reduces or prevents fractures, and that it reduced fractures among the elderly 100% over a three-year period. (Tab C Exhs. 10, 11, 14, 16.) Third, Lane Labs' advertisements claim that AdvaCAL is more absorbable, or in many cases, three times more absorbable, than other types of calcium. (Tab C Exhs. 8, 13-14, 17.)

The Defendants' "bone building" claim is made repeatedly in advertisements. (Tab C Exhs. 4-13.) The message repeated over and over by Lane Labs is that AdvaCAL is the "only" calcium product that can "build bone." (Tab C Exhs. 7, 12-13.)

Lane Labs also includes a chart in numerous advertisements (which, at least for some period, featured William Lane) touting AdvaCAL's supposed superiority over other calcium products. (Tab C Exhs. 10 and 11.) According to this chart, for post-menopausal women, AdvaCAL is nearly 4 times better than Calcium

Citrate Malate and nearly 3 times better than Calcium Citrate at building bone density.<sup>7</sup>

Defendants' deceptive superiority claims for elderly women are of a similar magnitude. Defendants claim that for an elderly population, AdvaCAL performs nearly 4 times better than Calcium Carbonate and approximately 1.6 times better than Calcium Hydroxy Apatite at improving bone density.<sup>8</sup>

Infomercials for AdvaCAL are replete with testimonials trumpeting the remarkable changes in bone density attributed to taking AdvaCAL. For example, a 28 year old reports a 20% increase in her bone density (Tab C Exh. 13); a 25 year old claims that her bone density increased by 50% after she took AdvaCAL (Tab C Exh. 13); a 39 year old claims that in one year her bone density went from 3% below average for her age to 20% above average (Tab C Exh. 12-13).

In addition to comparing AdvaCAL's supposed effectiveness in building bone to other calcium products' bone building effectiveness, Lane Labs has

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<sup>7</sup> On this chart, AdvaCAL shows a 2.6% increase in bone density over 2 years, compared to Calcium Citrate (approximately 1% over 2 years) and Calcium Citrate Malate (approximately -1.2% over 2 years). (Tab C Exhs. 10 and 11.)

<sup>8</sup> For this population, the Defendants claim that AdvaCAL increased bone density by approximately 3.1% over 2 years compared with Calcium Carbonate (approximately .8% over 2 years) and Calcium Hydroxy Apatite (approximately 1.9% over 2 years). (Tab C Exhs. 10 and 11.)

promoted the use of AdvaCAL in lieu of prescription treatments for osteoporosis. Through its website, Lane Labs provided a link for consumers to a newsletter published by the Health Sciences Institute (“The Battle for Your Bones”). (Tab C ¶ 12 Exh. 8). This newsletter contains a chart purporting to show that AdvaCal’s bone-building abilities are comparable or superior to Fosomax and Evista, two prescription products. (Tab C Exh. 8.) This chart purports to show that over a 2 year period, the change in spinal bone density was 3.2% for AdvaCAL, compared to 2% for Evista and 3.5% for Fosomax. (Tab C Exh. 8.) The article claims that “AAACa works as well or better than these expensive drugs, and without the substantial side effects and risks.” (Tab C Exh. 8.)

Lane Labs’ AdvaCAL advertisements also claim that it has fracture-reducing benefits. One chart referred to above indicates that there is a 100% fracture reduction for elderly patients over a 3 year period. (Tab C Exh. 10-11.) Other advertisements state that there were 0 fractures per 1000 patient years for AdvaCAL users compared with 357 for Calcium Carbonate users. (Tab C Exh. 14, 16.) A more general claim is made in an infomercial for AdvaCAL: “You don’t need to be in a nursing home because you broke your hip – all you have to do is take your AdvaCAL to prevent that.” (Tab C Exh. 13.)

Several of Lane Labs' advertisements focus on AdvaCAL's absorbability relative to other calcium products. These ads claim that AdvaCAL has been "clinically shown to be 3 times more absorbable than other calcium." (Tab C Exhs. 8.) This claim is repeated by William Lane and others in AdvaCAL infomercials.

There is no competent and reliable scientific evidence to support any of the above claims regarding AdvaCAL; and the Defendants' representations to the contrary misrepresent the tests and studies that pertain to AdvaCAL and the products to which Lane Labs claims it is superior. Therefore, under the terms of the Orders, a finding of contempt is warranted.

### **III. Legal Argument**

#### **A. Defendants are Liable for Civil Contempt**

The basic legal tenets governing civil contempt proceedings are well established under Supreme Court and Third Circuit authority. Courts possess the inherent authority to enforce compliance with their orders through civil contempt. Gunn v. University Committee to End the War in Viet Nam, 399 U.S. 383, 389 (1970); Shillitani v. United States, 384 U.S. 364, 370 (1966). "Civil contempt may be employed to coerce the defendant into compliance with the court's order and to compensate for losses sustained by the [defendant's] disobedience."

McDonald's Corp. v. Victory Investments, 727 F.2d 82, 87 (3d Cir. 1984).

The party seeking a finding of civil contempt must prove it by “clear and convincing evidence.” Id. See Roe v. Operation Rescue, 54 F.3d 133, 137 (3d Cir. 1995); Ardex Laboratories, Inc. v. Cooperider, 319 F.Supp.2d 507 (E.D. Pa. 2004); Al C. Rinaldi, Inc. v. Bach to Rock Music School, Inc. 279 F.Supp.2d 624, 627-28 (E.D. Pa. 2003). In order for a party to be held in civil contempt, a plaintiff must show that “(1) a valid court order existed, (2) the defendant had knowledge of the order, and (3) the defendant disobeyed the order.” John T. v. Delaware County Intermediate Unit, 318 F.3d 545, 552 (3d Cir. 2003) (quoting Harris v. City of Philadelphia, 47 F.3d 1342, 1326 (3d Cir. 1995)). The burden then shifts to the alleged contemnors to show why they were unable to comply with the order. FTC v. Affordable Media, LLC, 179 F.3d 1228, 1239 (9<sup>th</sup> Cir. 1999), cert. denied sub nom Lawson v. FTC, 534 U.S. 1042 (2001); In re Affairs with a Flair, 123 B.R. 724, 727 (Bankr. E.D. Pa. 1991).<sup>9</sup> As the discussion below demonstrates, the evidence that the Defendants were in contempt of the Orders against them is overwhelming.

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<sup>9</sup> Importantly, willfulness is not an element of contempt. Therefore, evidence of good faith does not bar the conclusion that a defendant acted in contempt. Robin Woods Inc. v. Woods, 28 F.3d 396, 399 (3d Cir. 1994).

**1. Defendants are Bound by Valid Court Orders of Which They had Knowledge**

The Defendants expressly stipulated to this Court’s final orders. They acknowledged receipt of the Orders (Tab C Exhs. 3 and 4), and have continued to do so through their multiple compliance submissions to the FTC. (Tab C ¶¶ 2-6.) As the president, chief executive officer and sole shareholder of Lane Labs, Defendant Andrew Lane has actual responsibility over the advertising, marketing, manufacturing, and distribution of Lane Labs’ products. (Tab C Exhs. 19, 21-26.) William Lane appeared in numerous Lane Labs advertisements for AdvaCAL and clearly participated in the marketing of the product. Thus, there is no question about whether each of the Defendants are individually subject to the Orders at issue and responsible for any violations of those Orders.

**2. The Defendants Disobeyed the Orders**

**a. The Defendants Have Violated the Order Against Lane Labs by Failing to Substantiate by Competent and Reliable Scientific Evidence Their Claim That Fertil Male Improves Fertility, and by Misrepresenting the Results of Studies of This Product**

As noted above, Lane Labs markets Fertil Male as a “natural supplement for male fertility,” and represents that Fertil Male has been “[c]linically shown to promote sperm count, sperm motility and semen production.” (Tab C Exh. 26 at

2.) Lane Labs makes both express and implied claims that Fertil Male boosts a man's fertility, as detailed in Section II.A.

Paragraph III of the Order against Lane Labs expressly bars the Defendants from making any

representation, in any manner ..., expressly or by implication, about the effect of [any] 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, defendants possess and rely upon *competent and reliable scientific evidence* that substantiates the representation. (Emphasis added.)

(Tab A ¶ III.) Similarly, Paragraph IV of the Order bars the Defendants from misrepresenting “in any manner, expressly or by implication, ... the existence, contents, validity, results, conclusions, or interpretations of any test, study or research.” (Tab A ¶ IV.)

Dr. Craig Niederberger, a urologist and male reproductive expert (Tab D ¶ 6), reviewed all of the data provided by the Defendants to substantiate their claims that *Lepidium Meyenii* (Maca roots),<sup>10</sup> Fertil Male's key ingredient, improved male fertility by increasing sperm count, motility, and production. (Tab D ¶¶ 6-12.)

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<sup>10</sup> Dr. Niederberger independently investigated whether there was other research on the effects of *Lepidium meyenii* on male fertility and found none. (Tab D ¶ 13.)

Dr. Niederberger concluded “that while *Lepidium meyenii* appears to function as a stimulatory agent for sexual behavior in animals and humans, [there is] no definitive, compelling, or analytically suggestive evidence that compounds based on [this substance] improve human male fertility.”<sup>11</sup> (Tab D ¶¶ 14.)

To reach his opinion, Dr. Niederberger looked both to animal and human studies. (Tab D ¶¶ 6-12.) As a general matter, he found that the animal studies on *Lepidium meyenii* focused on sexual behavior, not on the creation of sperm (Tab D ¶ 20), or male fertility. (Tab D ¶ 20.) Dr. Niederberger noted that “[w]here outcomes relating to *male fertility* were studied in animal models likely to simulate normal adult human male conditions, either statistically or clinically non-significant effects of *Lepidium meyenii* were reported.” (Emphasis added.) (Tab D ¶ 20.) Moreover, according to Dr. Niederberger, animal studies are insufficient, by themselves, to establish that *Lepidium meyenii* enhances human fertility. (Tab D ¶ 21.)

Dr. Niederberger likewise explained that the human studies on *Lepidium meyenii* are unconvincing and unreliable support for Defendants’ claim that this

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<sup>11</sup> Defendants’ own advertisements acknowledge the distinction between sexual behavior and fertility. See, e.g., Tab C Exh. 27 (“Sexual virility is the capability of having a pleasing sexual performance. This has nothing to do with the fertility status of a man. It is common for men to have perfectly normal sexual relations and have less than satisfactory fertility levels.”).

substance improves male fertility. (Tab D ¶¶ 21-22.) As with the animal studies, the human studies tended to address the effects of *Lepidium meyenii* on sexual behavior, rather than on male fertility. (Tab D ¶ 21.) Only two studies actually addressed human fertility. Dr. Niederberger identified two critical flaws with these studies: 1) the very small number of subjects (e.g., 12) (Tab D ¶¶ 21-23; and 2) the absence of a placebo group. (Tab D ¶¶ 21-22.)

Dr. Niederberger explains that the study by Dr. G.F. Gonzalez et al. (Tab D Exh. 2 at 8.2.1) consisted of only nine subjects (Tab D ¶ 21), a number far below the minimum number of subjects required in such a study. (Tab D ¶ 19.) Moreover, this study lacked any validity because it had no separate placebo group. (Tab D ¶ 21.) A placebo group is necessary to such a study “for a clear and critical reason.” (Tab D ¶ 18.) As Dr. Niederberger explains,

the reason relates to a statistical effect referred to as “regression to the mean.” Given any subjects with measurements related to a biological effect outside of the mean measurement for those subjects, such as a group of infertile men, they are *expected* to improve on subsequent testing simply because it is more likely that the next measurement will approach the mean. The only way to determine if such an improvement was due to chance or to a drug effect is to give a placebo to a separate group of subjects, and compare the outcomes of the placebo group to those of the group given the drug.

(Tab D ¶ 18.) (Emphasis in original.)

Defendants also rely on a more recent unpublished study by Martha Cuya partially funded by Lane Labs.<sup>12</sup> This study consisted of 47 infertile men and 12 men with normal sperm parameters who were given Maca and Maca-HAI. (Tab D ¶ 9.1.) As Dr. Niederberger notes, the authors of that study incorrectly suggest that the study was “double blind,”<sup>13</sup> because there was no placebo group, “a critical omission.” (Tab D ¶ 21.)

Moreover, none of the human studies addressing fertility detected “demonstrable changes in reproductive hormones coincident with *Lepidium meyenii* administration” (Tab D ¶ 21), making it unlikely that compounds based on this substance would improve fertility. (Tab D ¶ 21.) Thus, it is not reasonable, based on the limited and critically flawed studies submitted by the Defendants, to conclude that *Lepidium meyenii* will make a man more fertile. Indeed, the studies suggest that Defendants’ claims are probably untrue.

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<sup>12</sup> This study was not concluded until 2006 (Tab D ¶ 21), and thus, was not in the Defendants’ possession at the time they first began making claims that Fertil Male enhanced fertility. Under the Order against Lane Labs, it is necessary to have substantiation at the time the Defendants make a claim. (Tab A ¶ III.)

<sup>13</sup> Referring to this study as a “double-blind” study necessarily suggests the presence of a placebo group because it refers to a methodology in which investigators and subjects do not know who receives the placebo or the drug. (Tab D ¶ 18.)

Moreover, Dr. Niederberger explains that any competent and reliable scientific evidence that would substantiate the Defendants' claim that *Lepidium meyenii* – or Fertil Male – improves male fertility, would have to include:

- 1) animal studies that establish a plausible biological basis for improvements in male fertility (as distinguished from increased sexual activity);
- 2) human studies with a sufficient number of subjects that are designed and implemented in a manner that ensures that:
  - a) chance effects leading to observed improvements in fertility are excluded, traditionally by the inclusion of a placebo group separate from the treated group;
  - b) biases introduced by the investigators are excluded, traditionally by a double-blind design; and
  - c) clinically and statistically significant improvements are documented in outcomes that are relevant to an expected improvement in male fertility.

(Tab D ¶ 17.) The studies on which the Defendants rely to support their claims do not come close to meeting these basic requirements, and are thus not “competent and reliable scientific evidence” to support the Defendants' claims that Fertil Male increases a man's fertility. (Tab D ¶¶ 20-23.) The Defendants' further claim of

clinical support for this proposition is, therefore, demonstrably false as well. For these reasons, the Defendants' advertising of Fertil Male violates Paragraphs III and IV of the Order against Lane Labs and Andrew Lane. On this basis, the Defendants Lane Labs and Andrew Lane should be found in contempt for their advertising of this product.

**b. The Defendants Have Violated the Orders by Failing to Substantiate by Competent and Reliable Scientific Evidence Their Claims Regarding AdvaCAL, and by Misrepresenting the Results of Scientific Research**

As noted above, Paragraph III of the Orders requires that the Defendants have “competent and reliable scientific evidence” to substantiate representations about the effect of a product on the structure or function of the body or about any other health benefits of the product. (Tab A ¶ III.) Paragraph IV of the Orders bars the Defendants from misrepresenting “in any manner, expressly or by implication, ... the existence, contents, validity, results, conclusions, or interpretations of any test, study or research.” (Tab A ¶ IV.) The Defendants have violated both such provisions in their advertising of AdvaCAL.

To support their claims of superiority over other products, the Defendants rely on studies conducted by Dr. Takuo Fujita, the scientist who developed AdvaCAL. In 1999, Andrew Lane hired Dr. Robert Heaney of Creighton

University, a “world-recognized authority on calcium,” Metagenics, 1996 WL 615822 at \*19 (F.T.C. October 11, 1996), to evaluate Dr. Fujita’s research on AAACa (AdvaCAL). (Tab E ¶ 19 n.1.) At that time, Dr. Heaney informed the Defendants that they were relying on inadequate research to support their claim that AdvaCAL was superior to other forms of calcium. (Tab E ¶ 19 Exh. 3.) He suggested to Lane Labs that it conduct further independent testing on AAACa against another form of calcium to see which was more absorbable. (Tab E ¶ 19 Exh. 3.)

Thereafter, Lane Labs contracted with Creighton University to test the absorbability of AAACa (AdvaCAL) compared to Calcium Citrate (CitraCal). (Tab E ¶ 21a Exh. 8.) Far from finding AAACa superior, that study found Calcium Citrate to be more absorbable than AAACa. (Tab E ¶ 21a Exh. 8.) Notwithstanding these results, the Defendants proceeded to market AdvaCAL as superior to all other calcium products, including Calcium Citrate.

In connection with this contempt proceeding, Dr. Heaney again examined all of Dr. Fujita’s studies, along with the other materials the Defendants assert substantiate their claims, and concluded that this research does not constitute “competent and reliable” scientific support for the Defendants’ claims of AdvaCAL’s superiority. (Tab E ¶ 24.) The discussion below shows that there is

absolutely no support for Defendants' claims of superior absorbability, bone building, and fracture reduction.

**i. The Evidence Does Not Substantiate the Defendants' Claim that AdvaCAL is More Absorbable Than Other Types of Calcium**

The Defendants repeatedly claim that AdvaCAL is more absorbable than other calcium products. In fact, in numerous advertisements, Defendants claim that AdvaCAL is three times more absorbable than other calcium supplements. This claim is the predicate for all of the Defendants' claims of superiority in building bone and preventing fractures because, as Dr. Heaney explains in his declaration, once absorbed, all calcium loses its source identity. (Tab E ¶ 11.) "For the same amount of calcium absorbed, all calcium salts and supplements produce approximately the same effect." (Tab E ¶ 12.) Any superiority claim, therefore, rests upon proof of greater absorbability. As the discussion below details, neither the evidence relied upon by the Defendants, nor the body of scientific evidence on the subject of absorbability of calcium, supports the Defendants' claims that AdvaCAL is more absorbable than other calcium compounds. Therefore, not only must Lane Labs' claim of superior absorbability fail, but all of its other claims of superiority as well.

The Defendants' claim that AdvaCAL is "more absorbable" is unsubstantiated. First, the Defendants proffer no human studies to support their claims of superior absorbability.<sup>14</sup> There are human studies, however, that call into question the Defendants' claims. For instance, Dr. Heaney observed that data in the study reported in an article published by Dr. Fujita in 1996 in *Calcified Tissue International*, suggested that AdvaCAL was not absorbed at all. In that paper, Dr. Fujita et al. reported a fall in urinary calcium excretion in the group treated with AAACa. (Tab E ¶19 at 15.) Calcium absorption, however, is never associated with a fall in urine calcium. (Tab E. ¶ 19 at 15.) While Dr. Heaney rejects these implausible results as demonstrating a failure of study design (Tab E ¶ 19 at 15), he nevertheless observes that "the urine calcium, as reported, shows no evidence whatsoever of calcium absorption, and without calcium absorption, there can be no effect on bone mineral density." (Tab E ¶ 19 at 15.)

Furthermore, the Defendants' claim of superior absorbability is directly contradicted by the study commissioned by Lane Labs and conducted by Dr. Heaney before the Defendants began advertising and marketing AdvaCAL. In that

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<sup>14</sup> The animal studies they rely upon compare absorption of AACa to this product with HAI (Tab E ¶21a at 18), a seaweed derived compound ostensibly used to enhance the absorbability of AACa.

study, Dr. Heaney concluded that AdvaCAL is not as well absorbed as Citracal. (Tab E ¶ 21a at 19.)

The Defendants also repeatedly state that AdvaCAL is “three times more absorbable” than other calcium. (Tab C ¶ 21a at 18.) Dr. Heaney explains that scientifically this cannot be true. “[T]he calcium absorption fraction for most calcium sources (including milk) at a 300 mg load is approximately .30...” (Tab E ¶21a at 18.) “[F]or a source to be 3 times as absorbable as that, the fractional absorption would have to be .9 (or 90% of the ingested calcium absorbed). Except in low birth weight newborns with an immature gut, no calcium absorption fractions remotely close to .90 have ever been reported.” (Tab E ¶ 21a at 18.) Therefore, as a matter of scientific fact, the Defendants’ claim that AdvaCAL is three times more absorbable than other calcium is patently false. There is no substantiation for such a claim.

In summary, the existing evidence, including the evidence directly relied upon by the Defendants, does not support the Defendants’ claim that AdvaCAL is more absorbable than other types of calcium, and certainly not the much stronger claim that the product is “three times more absorbable.” This claim, as well as the Defendants’ other claims that are based on an assumption of greater absorbability,

are therefore unsubstantiated. On this basis, the Defendants should be held in contempt of the Order.

**ii. The Evidence Does Not Support the Defendants' Claims that AdvaCAL is Superior to Other Calcium or Prescription Products at Building Bone or Increasing Bone Mineral Density**

In addition to making unsubstantiated claims that AdvaCAL is more absorbable than other calcium products, Lane Labs claims that AdvaCAL is superior to other products at building bone or increasing bone mineral density. These claims, too, are not substantiated by the available evidence.

The Defendants do not explain what they mean by “build bone.” As Dr. Heaney explains, no calcium product is “a sufficient stimulus by itself to cause more bone to be formed,” (Tab E ¶ 21b at 20), although when taken with a bone active agent such as Eli Lilly’s Forteo, calcium may *help* to build bone. (Tab E ¶ 21b at 20.) In contrast to Forteo, which actually builds new bone, all that calcium can do is reclaim bone that has been undergoing remodeling (“that has been out of commission”). (Tab E ¶21b at 20-21.) This can result in a measurable increase in bone mineral density, although it does not literally indicate the introduction of new bone. (Tab E ¶ 21b at 21.) Even if one assumes, *arguendo*, that a discernible increase in bone mineral density brought about by the

reclamation of bone is tantamount to “building bone,” then AdvaCAL shares in the credit for that increase along with other calcium products. (Tab E ¶ 21b at 21.) The Defendants have not provided any evidence that would support their claim of superiority in this regard, however. (Tab E ¶ 21b at 21.)

According to Dr. Heaney, the studies relied upon by the Defendants to support their claims of superiority in increasing bone mineral density are defective in critical respects. One study by Dr. Fujita published in 1996 in *Calcified Tissue International* compared AAACa (AdvaCAL) to Calcium Carbonate and a placebo. (Tab E ¶ 19 at 13 Exh. 5.) That study consisted of elderly hospitalized women with a mean age of 80. (Tab E ¶ 19 at 13.) The data reported improvements for all three groups at 24 months. According to Dr. Heaney, this data must have been erroneous because “placebo-treated, 80-year-old women do not gain bone over a 24-month period.” (Tab E ¶ 19 at 13.) This anomaly is explained by a high drop-out rate and a defective study design. (Tab E ¶ 19 at 13-14.) The three groups began with 19, 17, and 20 persons, respectively, but at 24 months, had only 5, 6, and 7 remaining participants. (Tab E ¶ 19 at 13-14.) Dr. Heaney surmises, based on his experience, that the drop outs were the sickest and frailest individuals, and accordingly, the ones with the lowest starting bone mineral density values. (Tab E ¶ 19 at 14.) Every time such an individual dropped out of the study, the average

























