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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.

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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

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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 cha.

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<sup>3</sup>

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promoted the use of AdvaCAL in lieu of pres



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

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**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.)

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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,

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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 anim

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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. Niederber

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

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.)

Therea



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 D

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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



(Tab E ¶ 19 at 17.) In addition, there was no statistically significant difference in the results for AdvaCAL and Calcium Carbonate in increasing radial bone mineral density. (Tab E ¶ 19 at 17.) The groups were not well matched in terms of age and baseline bone mineral density, and the sample sizes were too small (between 6 and 11 individuals per group). (Tab E ¶ 19 at 17.) As Dr. Heaney notes, “[t]his study ... produced an indeterminate result. Such studies should not be done, as they are clearly underpowered, and if done, should not be published.” (Tab E ¶ 19 at 17.)

The Defendants graphically depict their claims of superiority in increasing bone density on a chart seen in advertisements running from 2003 to 2006. (Tab C Exhs. 10 and 11.) One of the graphs in these advertisements purports to show two-year spinal bone density changes for both post-menopausal women and elderly women. (Tab C Exhs. 10 and 11.) Defendants depict AdvaCAL as increasing spinal bone density in post-menopausal women nearly 4 times better than Calcium Citrate Malate and nearly 3 times better than CalciumTtter thu

purportedly support the representations made in that advertisement. (Tab C Exhs. 10 and 11.)

This chart deceptively conveys that head-to-head studies exist that directly compare AdvaCAL to the other products referenced. In fact, Defendants can point only to defective studies comparing AdvaCAL to Calcium Carbonate. (Tab E ¶ 19 at 13, 17.) AdvaCAL has not been directly compared with the other supplements in the chart and the data involving those supplements “come from very different studies involving very different populations and treatment conditions.” (Tab E ¶ 21c at 24.) Dr. Heaney also explains that “... the figures cited for such products are not representative of the totality of the evidence with the respect to the individual sources used in this comparison.” (Tab E ¶ 21c at 24.)

The data for Calcium Citrate Malate selectively displayed in the chart illustrates this point. Calcium Citrate Malate is “generally recognized to be the best absorbed calcium supplement in widespread market use, certainly at least as good as, if not better than, for example, calcium citrate or calcium carbonate.” (Tab E ¶ 19 at 11-12.) Given this, the comparative data displayed in the chart, showing a 1% increase in bone density for Calcium Citrate and a *decrease* of 1.2% for Calcium Citrate Malate over two years (Tab C Exhs. 10 and 11) is “paradoxical” (Tab E ¶ 19 at 12), and is not a result that would be seen in a side-



by-side study. As Dr. Heaney further explains, “[t]he

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subjects and conditions. No valid comparison between and among these products can be made based on these studies. Moreover, the studies the Defendants rely on to justify their claim of AdvaCAL's superiority in building bone mineral density are critically flawed and unreliable. The Defendants have, accordingly, violated Paragraphs III and IV of the Order and should be held in contempt.

**iii. The Evidence Does Not Support the Defendants' Claims that AdvaCAL is Superior to Other Calcium Products in Avoiding or Reducing the Risk of Fractures**

In addition to claiming that AdvaCAL is more absorbable than other calcium brands, and more effective at building bone density, Lane Labs claims that by taking AdvaCAL, one will avoid fractures. This claim is captured in a sweeping statement in an AdvaCAL infomercial, "you don't have 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. 11.) The Defendants also make the fracture reduction claim in advertisements comparing AdvaCAL to other products. For instance, in the chart featured so prominently in AdvaCAL advertisements (Tab C Exhs. 10 and 11), the Defendants claim that over a 36-month period, AdvaCAL reduces fractures among elderly patients 100%. This advertisement compares AdvaCAL's supposed fracture reduction rate to those of Calcium Citrate Malate, Calcium Carbonate and

Calcium Hydroxy Apatite. (Tab C Exhs. 10 and 11.) In another advertisement  
with the he

referred to above, *supra* at 23. (Tab E Exh. 5.) Both the claim of “100% fracture reduction” and a “rate of 0 fractures per thousand patient years” are purportedly derived from that underlying study, which is wholly inadequate support for those claims. Dr. Heaney points out that

the fracture figures cited in that study are impossible to interpret since they are expressed as numbers of fractures per 1,000 subject years, without providing the number of subject years actually experienced; moreover the absolute number of fractures is, itself, not even mentioned. Since the study duration was 2.5 years, and by the end of the study, three-fourths of the subjects had dropped out, it can be roughly estimated that there were perhaps no more than 10 actual person years of observation in each group. While the paper records no fractures in the AAACa-treated group, a finding of 0 out of 10 is actually consistent with a true fracture rate of anywhere from 0% to as high as 31%. The confidence intervals for the estimated fracture rates for the three groups are not given, and should have been.

(Tab E ¶ 19 at 15-16.)

The strongest evidence that these claims are unsubstantiated, however, comes from Dr. Fujita himself. In a 1999 interview, he observed that the study published in 1996 in *Calcified Tissue International* was inconclusive as to the effect of AdvaCAL on fractures:

Of course, any increase in [bone mineral density] promises fewer fractures and for women in their eighties, there was no increase in fractures while they were on AAACa, but out of the thirty-placebo-controlled subjects there were three fractures. This number is not large enough but it suggests that AdvaCAL prevents decrease in bone strength. So it's quite possible that AdvaCAL would prevent fractures.



“Only calcium I know of that can increase bone density.” (Tab C Exh. 13 at

Exh. 13.)

William Lane's claims of AdvaCAL's superiority are not adequately substantiated, and misrepresent the results of tests and studies on AdvaCAL and other calcium products. Therefore, William Lane, along with Defendants Lane Labs and Andrew Lane, should be held in contempt of the Order against him.

**C. Consumers Must be Compensated for the Defendants' Contumacious Behavior<sup>20</sup>**

Lane Labs claims that Fertil Male enhances a man's fertility, but there is no competent and reliable scientific evidence to support this proposition. Indeed, the evidence suggests that Lane Labs' claims regarding Fertil Male are probably false. Notwithstanding these facts, Lane Labs marketed and sold Fertil Male to thousands of people.

Lane Labs similarly marketed and sold AdvaCAL without any substantiation for its claims of superiority over other calcium products and comparability or superiority to prescription products used to treat osteoporosis.

Based on these extrao

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The Defendants' sales – on the order of millions of dollars – translate into real losses by consumers – losses for which consumers are entitled to be compensated. Accordingly, the FTC asks that this Court, after hearing of the matter and assessing the evidence of damages arising from the Defendants' order violations, exercise its discretion and award full compensation to the victims of the Defendants' wrongful and contumacious advertising.

#### **IV. Conclusion**

For all of the foregoing reasons, the FTC asks that this Court issue an order, requiring Defendants to show cause why they should not be held in contempt.

Dated: January 12, 2007

WILLIAM BLUMENTHAL

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