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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

ThermoLife International, LLC,
Plaintiff/Counterdefendant,
vs.
Gaspari Nutrition, Inc., et al.,
Defendants/Counterclaimants.

No. CV-11-01056-PHX-NVW

ORDER

Before the Court are the following motions:

1. Gaspari Nutrition, Inc.'s Motion to Exclude Portions of Response Report and Areas of Testimony of Dr. Thomas Sox (Doc. 178);

2. Gaspari Nutrition, Inc.'s Motion to Exclude Survey, Report and Testimony of James T. Berger (Doc. 181);

3. Plaintiff's *Daubert* Motion to Exclude the Expert Report, Response Report, and Testimony of Jim Prochnow (Doc. 190);

4. Gaspari Nutrition, Inc.'s Motion to Exclude Certain Testimony and Opinions of Ron Epperson (Doc. 201);

5. Gaspari Nutrition, Inc.'s Motion to Exclude Report and Testimony of Ryan Hornbuckle (Doc. 202);

6. Plaintiff's *Daubert* Motion to Exclude the Expert Report and Testimony of Stephen Clarke (Doc. 205);

7. Gaspari Nutrition, Inc.'s Motion for Summary Judgment (Doc. 203);

8. Motion for Summary Judgment on Gaspari Nutrition Inc.'s Counterclaims (Doc. 206) by ThermoLife International, LLC;

9. Plaintiff's Motion for Sanctions Due to Gaspari Nutrition Inc.'s Intentional Destruction of Evidence and GNI's Efforts to Conceal Its Wrongful Conduct (Doc. 216);

10. Motion to Strike Declaration of Ted Willard and Portions of Reply That Rely on the Willard Declaration (Doc. 267) by Gaspari Nutrition, Inc.;

11. ThermoLife's Motion for Sanctions Due to Defendant's Failure to Produce Relevant Documents in Discovery (Doc. 355); and

12. Gaspari Nutrition, Inc.'s *Motion in Limine* No. 1 to Exclude Certain FDA Statements (Doc. 319).

In addition to considering the foregoing motions and the responses and replies thereto, the Court has considered ThermoLife International, LLC's Supplemental Brief (Doc. 341) and Gaspari Nutrition, Inc.'s Response (Doc. 360).

The briefs and statements of facts alone come to 735 pages. With attachments, the paper reaches 35 inches and 84 pounds. But at the bottom of the 735 pages, 35 inches, and 84 pounds, there is no lawsuit.

I. BACKGROUND

ThermoLife International, LLC ("TLI") and Gaspari Nutrition, Inc. ("GNI") have been competitors in the business of selling dietary supplement products related to bodybuilding. Ron Kramer is the president of TLI. Rich Gaspari is the president of GNI.

The United States Food and Drug Administration ("FDA") regulates both finished dietary supplement products and dietary ingredients under the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), an amendment to the Food, Drug, and Cosmetic Act ("FDCA").

In its First Amended Complaint, TLI alleges eleven counts, nine of which are for false advertising under 15 U.S.C. § 1125(a)(1)(B), which is § 43(a)(1)(B) of the Lanham Act. TLI alleges that GNI has engaged in false advertising by marketing and selling its

products as "safe," "natural," "DSHEA-compliant," and "legal." The allegations concern four GNI products sold as dietary supplements: Novedex XT (sold January 2005 to October 4, 2010), Halodrol Liquigels (sold July 2006 to July 2010), Halodrol MT (sold September 2009 to April 2011), and SuperPump 250 (sold January 2005 to July 2010). The First Amended Complaint also alleges common law unfair competition and tortious interference with business and business expectancy.

In its Counterclaim, GNI alleges unfair competition, trade disparagement, and, under 15 U.S.C. § 1125(a), false designations of origin, false descriptions, false advertising, and unfair competition. Among other things, GNI claims that TLI made false statements regarding GNI's SuperPump 250, Novedex, Halodrol, and Vasotropin products.

II. EXPERTS

A. Legal Standard

Trial courts must ensure that any and all evidence admitted is both relevant and reliable. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). Rule 702 of the Federal Rules of Evidence provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

B. James T. Berger, TLI's Consumer Survey Expert

Mr. Berger's expert report dated May 29, 2013, focuses on an Internet survey intended to determine if certain statements made by GNI in its advertising of Novedex

XT, Halodrol[1] MT, and Halodrol Liquigels were material to a consumer's buying decision. Mr. Berger reviewed pleadings and discovery provided to him by TLI and concluded that, although GNI's advertising was worded in many different ways, when GNI's advertising of Novedex XT, Halodrol MT, and Halodrol Liquigels "are viewed as a whole[,] you see that the defendant advertised these products as 'Natural,' 'Legal,' 'DSHEA-compliant' and 'Safe.'" Finding it impractical to test each specific statement, Mr. Berger's survey was designed to determine whether statements that a product was "Natural, "Legal," "DSEA-compliant," "Safe," and included clinically proven effect doses of raw materials affected consumers' buying decisions.

Mr. Berger's report does not state when the survey was conducted or how survey participants were solicited, only that they were limited to males age 16 and over who had purchased Novedex XT, Halodrol MT, Halodrol Liquigels, or other testosterone-boosting supplements. None of the respondents could have been a current user of Novedex XT, Halodrol MT, or Halodrol Liquigels at the time of the survey because those products had not been sold for at least two years. The report makes no attempt to show that survey respondents were representative of potential consumers of GNI's or TLI's testosterone-boosting products.

Each of 259 respondents was assigned to one of four surveys regarding one of the products he had purchased: 64 responded to Novedex XT questions, 65 responded to Halodrol MT questions, 63 responded to Halodrol Liquigels questions, and 67 responded to questions about other testosterone-boosting supplements. Each of the surveys related to the GNI products began with a paragraph stating that certain GNI products had been recalled and describing the product's potential adverse reactions and harmful effects, such as decreased sperm production, infertility, aggressive behavior, adrenal insufficiency, kidney failure, liver dysfunction, shrinkage of the testes, and increased risk

[1] Mr. Berger's report consistently misspells "Halodrol" as "Haladrol."

of heart attack, stroke, and death. The first question asked the respondent whether he was aware of this report of the potential side effects of the specific product. The survey also stated if a product was not DSHEA-compliant, it "wasn't legal." Subsequent questions had three multiple-choice responses, worded to obtain a response favorable to TLI. For example:

> In purchasing a dietary supplement, how important is it that the supplement contains ingredients that are legal:
>
> - Very important; I would never purchase a supplement I knew contained an illegal drug
> - Somewhat important; I would prefer to purchase a supplement that did not contain an illegal drug
> - Not important; in purchasing a supplement, I do not consider whether the product might contain an illegal drug
>
> If you were using a testosterone boosting supplement that was advertised as a natural way to trigger a potent and sustained physiological response and you were to discover the product used unnatural ingredients, what would be your reaction:
>
> - I would stop using the product immediately and not use any other testosterone boosting supplement
> - I would stop using the product immediately and seek out another product that was known to use "natural" ingredients
> - I would continue using the product

The survey did not ask the respondents how likely they would be to purchase a product primarily because it claimed to be "natural, "legal," "DSEA-compliant," "safe," and/or include clinically proven effect doses of raw materials. It did not ask whether respondents were more likely to purchase a product with such advertising instead of a product without such advertising. It did not ask how important DSHEA-compliance was

to their purchasing decisions, but instead stated that if a product was not DSHEA-compliant, it "wasn't legal" and questioned whether they would purchase "an illegal drug." The survey questioned whether respondents who had previously purchased testosterone-boosting products would have continued to purchase those products if they knew they were not safe, natural, and legal or would have chosen a product that actually was safe, natural, and legal. Because respondents already had used the products, it cannot be determined how their satisfaction with the effectiveness of the products influenced their responses regardless of any advertising. Thus, even if the survey sample had been representative of potential consumers, the questions were not designed to determine the materiality of advertising regarding whether a product was safe, natural, legal, and DSHEA-compliant.

From the survey, Mr. Berger concluded: "Clearly, users of testosterone boosting supplements are very careful and mindful of the products they use. They want to make sure the products they use are: safe, legal, in compliance with U.S. regulations, contain "NATURAL" ingredients, deliver ingredients in the proper potency." He also concluded that "an extremely high percentage of respondents that had previously taken one of the [GNI] products at issue in this lawsuit indicated [if] they were informed that [GNI's] advertising was false, they would stop using the product and seek out another product in the same product line with advertised benefits." From which Mr. Berger concluded: "This suggests that a substantial portion of [GNI's] customers would have purchased a competitor's product but for [GNI's] false advertising."

Mr. Berger's survey, report, and testimony are not based on sufficient facts or data and are not the product of reliable principles and methods. The survey was biased, and there is no evidence that the survey sample was representative of potential consumers. The survey questions were not designed to determine whether GNI's advertising of Novedex XT, Halodrol MT, and Halodrol Liquigels as safe, legal, natural, and DSHEA-compliant was material to potential consumers' buying decisions. Therefore, GNI's

Motion to Exclude Survey, Report and Testimony of James T. Berger (Doc. 181) will be granted.

C. Dr. Thomas Sox, TLI's Liability Expert

In his expert report dated May 31, 2013,[2] Dr. Sox states that TLI engaged him to evaluate the veracity of GNI's advertising and to provide opinions regarding whether GNI's Novedex XT, Halodrol[3] MT, and Halodrol Liquigels were DSHEA-compliant and safe; whether Novedex XT was natural; and specific questions about whether TLI's testing of certain products supports certain conclusions. GNI moves to exclude portions of Dr. Sox's June 24, 2013 Report, which supplements his May 2013 Report and responds to GNI's May 28, 2013 expert disclosures, and areas of Dr. Sox's testimony. (Doc. 178.)

1. Opinions Related to ETH and Vardenafil

GNI contends that Dr. Sox's opinions regarding ETH and Vardenafil were untimely produced for the first time in his June 24, 2013 Report (pages 9-11), and that the June 24, 2013 Report raises new matters, not merely a supplement to the May 2013 Report. On May 15, 2013, the Court granted the parties' joint motion to extend expert disclosure deadlines, extending "the deadline for the party with the burden of proof to disclose expert reports" to May 31, 2013, and the deadline for response expert reports to June 24, 2013. (Doc. 144). TLI contends that on May 31, 2013, it disclosed Dr. Sox's opinions that it intends to rely on in support of the claims for which it bears the burden of proof, and on June 24, 2013, it disclosed Dr. Sox's opinions that it intends to rely on in its defense against GNI's counterclaim. In reply, GNI contends that the initial scheduling order (Doc. 60) said that "the *propounding* party . . . shall provide full and complete

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[2] The date underneath his signature is May 31, 2012, and his June 24, 2013 Report states that he previously submitted a report on May 28, 2013, but the date in the footer of his first report is May 31, 2013.

[3] Dr. Sox's report misspells "Halodrol" as "Haladrol."

expert disclosures." However, the May 15, 2013 Order uses the language agreed to and proposed by the parties, *i.e.*, "party with the burden of proof."

GNI also contends that TLI is offering Dr. Sox's opinions regarding ETH and Vardenafil to provide an affirmative defense, *i.e.*, TLI's statements about GNI's products were true and therefore TLI is the party with the burden of proof. It need not be decided now which party bears the burden of proof and whether TLI's disclosure of Dr. Sox's opinions regarding ETH and Vardenafil was timely, because GNI had opportunity to address them in a rebuttal report by July 5, 2013, and questioned Dr. Sox regarding them in deposition.

GNI further contends that merely the subject of ETH and Vardenafil was not timely disclosed before the close of fact discovery. Because the Discovery Master concluded that GNI had not satisfied its discovery obligations and ordered additional production that was not completed before the close of fact discovery, and the parties have been permitted to use the late discovery to supplement their briefing on all of the motions decided in this Order, Dr. Sox's opinions related to ETH and Vardenafil will not be excluded for untimely disclosure.

2. Opinions Regarding the Safety of GNI's Products

In his May 31, 2013 Report, Dr. Sox poses the question: "Are the results of the Willoughby and Ziegenfuss studies sufficient to substantiate a claim that Novodex[4] is safe?" He concludes:

> A well recognized procedure [Generally Recognized as Safe ("GRAS")] is used to establish the safety of new dietary ingredients. The ingredients in Novodex XT have not been subjected to this procedure, and they cannot be safe. The Willoughby and Ziegenfuss studies were too small and too narrow in its subject base to establish the safety of the ingredients. . . . Indeed Gaspari Nutrition, Inc. admitted in its October 7, 2010 Recall-Firm Press Release, that Novodex XT

[4] Dr. Sox consistently misspells "Novedex" as "Novodex."

> could potentially cause a host of adverse events . . . . Furthermore, all evidence contradicts the safety claims made in Gaspari Nutrition Inc.'s advertising. Novodex XT was not safe.

(Doc. 178-1 at 29.) In deposition, Dr. Sox conceded that the DSHEA does not require Novedex to be subjected to the GRAS procedure because Novedex XT is a dietary supplement, not a food additive. He explained that GRAS provides a means for being able to establish that a product is safe and is the current industry norm. But he does not provide any support for his conclusion that because the ingredients in Novedex XT have not been subjected to the GRAS procedure, "they cannot be safe." Although he may opine regarding the sufficiency of GNI's proof to support its claim that Novedex XT is "safe," his report does not support his conclusion that Novedex XT "was not safe."

Regarding the Halodrol products, Dr. Sox poses the question, "Were the ingredients in Halodrol safe?" He states: "Halodrol contained steroidal ingredients such as 5-alpha (5-alpha-androstane-3,6,17-trione) and 6-OXO (4-androstene-3,6,17-trione)." Earlier in the report, Dr. Sox refers to "3,17-diketo-androst-1,4,6-triene (or ATD), an active ingredient in Novodex XT," but he does not state that Halodrol contains ATD. (Doc. 178-1 at 7.) He opines:

> Published safety data, as required for GRAS status, apparently do not exist for ATD and 6-OXO. ATD and 6-OXO were apparently never subjected to the well-established safety evaluation process that is used for determining the safety of new drugs, food ingredients, or food additives. . . . A new ingredient that has not been subjected to this well-established safety evaluation process cannot be considered safe. Given the potential for adverse effects on human health, ingredients not supported by data from such a process are probably best regarded as unsafe.

(*Id.* at 30-31.) His recommendation that ATD and 6-OXO "are probably best regarded as unsafe" is not helpful to a jury that must decide whether GNI's advertising that Halodrol is safe is, in fact, false.

Dr. Sox states that ATC and 6-OXO are "putative aromatase inhibitors," and he relies on a study of female breast cancer patients treated for five years with a prescription aromatase inhibitor. Because this study found a correlation between the prescription aromatase inhibitor and osteoporosis and cardiovascular events in women with pre-existing atherosclerosis and increased cholesterol levels, he opines, "If ATD and 6-OXO was [*sic*] subjected to similar long-term testing in men, similar adverse effects might be noted." In deposition, Dr. Sox admitted that the intended users of Halodrol were males and that he was not familiar with the labels on the Halodrol products, which warned that it was not to be used by persons under the age of 21, women, or people who have cancer or have ever had cancer.

In his report Dr. Sox mentioned a study involving "elderly men," but did not discuss its results. GNI contends that its products were not intended for "elderly men," but the labels do not indicate an upper limit for the age of males for which the products are intended.

In his May 31, 2013 Report, Dr. Sox concludes:

> Halodrol cannot be considered safe, since it contains ingredients which have not been demonstrated to be safe. . . . Given the lack of safety data for Halodrol, and the known side effects of compounds working by the same mechanism as ATD and 6-OXO, a reasonable and precautionary assumption is that it is not safe.

(*Id.* at 30.)

It would not be helpful to the jury to hear Dr. Sox's opinion that GNI did not have sufficient research to prove that Novedex XT and the Halodrol products were "safe," when the issue they would need to decide is whether, in fact, the products were "safe." Dr. Sox's conclusion that they are not "safe" is not based on sufficient facts or data or the product of reliable principles and methods. Moreover, the jury likely would be confused and easily misled without a standard for determining what is "safe."

Therefore, Gaspari Nutrition, Inc.'s Motion to Exclude Portions of Response Report and Areas of Testimony of Dr. Thomas Sox (Doc. 178) will be granted.

D. Ryan Hornbuckle, TLI's Market Expert

In his expert report dated May 31, 2012,[5] Mr. Hornbuckle states that TLI engaged him to evaluate how GNI's Novedex XT, Halodrol MT, and Halodrol Liquigels products competed with certain of TLI's products and to provide an opinion regarding whether, but for GNI's false advertising, TLI's testosterone-boosting dietary supplement products would have performed better in the marketplace. Mr. Hornbuckle's report did not address GNI's SuperPump 250, which competed in a separate category known as "pre-workout products."

In deposition Mr. Hornbuckle testified that he had never previously conducted the type of market analysis he did for this case, and he created the methodology he used by relying on subjective factors based on personal experience. He described what he did as "a subjective analysis based on my experience." Further, he said:

> [T]his is purely based on my history in the business being able to look at winners and losers, and also based on some of the traditionally frowned-upon things in the business, like—by the consumer. For example, proprietary blends, things that are shrouded in proprietary blends tend to get lower marks from the—the consuming public, but not completely disregarded.

To establish the market for 2005-2010, Mr. Hornbuckle began by identifying only products that were advertised in three random monthly issues, for each of the years 2005-2009, of *Joe Weider's FLEX* magazine and distributed by GNC. Next, he narrowed the list of products to include only those that "1) did not engage in false advertising, 2) only contained DSHEA compliant ingredients, and 3) were owned by companies/brands recognized for product authenticity and viewed by consumers as trustworthy." To

[5] The date of 2012 could be a typographical error.

narrow the list to products that would be eligible for dollars captured by falsely advertised items, he removed products that contained "banned, illegal, or otherwise unapproved dietary ingredients" (including Novedex XT and Halodrol Liquigels) and "brands or products not viewed as serious competitors." In doing so, Mr. Hornbuckle relied on Mr. Berger's survey and the conclusions of Mr. Berger and Dr. Sox.

Using "the winnowed list from 2007, 2008, and 2009," Mr. Hornbuckle then assigned weights to six products based on certain factors. For each of the three years, he gave positive weight to products that had a heavily advertised brand and negative weight to products that had a proprietary blend or "old technology." For 2007, he gave negative weight to a product that had "unsubstantiated technology." For 2008 and 2009, he gave negative weight to a product that had "Sarm technology." He admitted that he could have used additional factors or criteria, such as product pricing, packaging design, and dosing instructions. And for the four factors he used, he testified that the weight he assigned was "arbitrary . . . a subjective thing."

Mr. Hornbuckle also reviewed website forum posts from Bodybuilding.com, which he concluded indicated that "consumers were very often making a choice between [TLI's] Testosterone Boosting products and GNI's Testosterone Boosting products." Mr. Hornbuckle states the following conclusions:

> For the years 2006 to 2008—the years when GNI and [TLI] competed head-to-head on the GNC shelives—[TLI] would have received over 46% of GNI's sales volume in 2006, 40% of GNI's sales volume for 2007, and close to 42% of GNI's volume in 2008. These numbers are the result of culling and weighting a list of the GNC advertised products that were 1) truthfully advertised, 2) contained DSHEA-compliant ingredients, and 3) were from trusted and authentic brands. The positive weight was added if products were heavily advertised (and devoid of false claims) as this would have—at least in the short-term—a favorable impact on sales, and the negative weight was subtracted for obscuring formulation

> details or for using outdated or irrelevant technologies or ingredients. . . .
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> . . . .
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> If not for the false advertising of unapproved dietary supplements by [GNI], [TLI] would have undoubtedly performed better in the marketplace as a whole, and would have captured a conservative average of 42.7% of GNI's sales volume from 2005 to 2010 in the Testosterone Booster category—a category where Halodrol and Novedex compete directly with [TLI] branded products . . . across the entire domestic Sports Nutrition marketplace.

Mr. Hornbuckle also opined from experience that in any category of dietary supplements a leader typically emerges and earns a disproportionate amount of the market share as success for any dietary supplement makes that product more popular. Therefore, in Mr. Hornbuckle's opinion, TLI's increased sales likely would have made it a leader in the testosterone-boosting category and caused it to capture more than GNI's sales.

Mr. Hornbuckle's report and testimony are not based on sufficient facts or data, not the product of reliable principles and methods, and likely to mislead the jury. He made up a methodology, excluded from consideration most of the products in the market, and gave the appearance of numeric accuracy by arbitrarily assigning weights to a few products based on his subjective feelings about what would affect consumers' purchasing decisions. Moreover, TLI has not shown that Mr. Hornbuckle is qualified to opine regarding whether, but for GNI's false advertising, TLI's testosterone-boosting dietary supplement products would have performed better in the marketplace and what percentage of the market TLI would have captured. Therefore, Gaspari Nutrition, Inc.'s Motion to Exclude Report and Testimony of Ryan Hornbuckle (Doc. 202) will be granted.

E. Ron Epperson, TLI's Damages Expert

In his expert report dated May 31, 2013, Mr. Epperson states that he was retained on behalf of TLI to review and analyze damages "in connection with" TLI's claims for

false advertising, unfair competition, and tortious interference against GNI. Under 15 U.S.C. § 1117(a), if liability is established under § 1125(a)(1)(B) for false advertising, subject to the principles of equity, a plaintiff is entitled "to recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action." "In assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed." 15 U.S.C. § 1117(a).

1. GNI's Profits Related to the False Advertising of Novedex XT, Halodrol Liquigels, Halodrol MT, and SuperPump 250

Mr. Epperson concludes that GNI's gross sales revenues for Novedex XT, Halodrol Liquigels, Halodrol MT, and SuperPump 250 over the period of January 2000 through December 2011 equals $92,203,999. He uses a period beginning in January 2000 although TLI has alleged that GNI's supplements competed with TLI's products from 2005 to 2010, not 2000-2004, and does not allege that GNI made false statements about Novedex XT, Halodrol Liquigels, Halodrol MT, or SuperPump 250 before 2005.

Mr. Epperson further concludes that GNI's gross profits for these products over the twelve-year period totals $54,871,352 and "GNI's disgorgement of profits related to the Violative Products equals $54,871,352." But he provides no basis for his conclusion that all of GNI's profits were causally related to its false advertising and therefore must be disgorged.

Moreover, these totals include $60,276,376 in gross sales for SuperPump 250 and $28,728,210 in gross profits for SuperPump 250. Thus, Mr. Epperson includes $28,728,210 from sales of SuperPump 250 in the amount that GNI should disgorge even though TLI did not sell a competing product. Mr. Epperson gives no explanation for concluding that TLI was damaged by GNI's allegedly false advertising of SuperPump 250.

2. TLI's Profits Lost Due to GNI's Alleged False Advertising

Mr. Epperson also calculates TLI's lost profits due to false advertising of Novedex XT, Halodrol Liquigels, and Halodrol MT. He excludes SuperPump 250 from this

analysis, apparently because no TLI product directly competed with SuperPump 250. He relies on Mr. Berger's opinion that "approximately 63% of individuals who use testosterone boosting dietary supplements that were advertised as being legal and meeting safety stand[ar]ds, but were not legal or did not meet safety standards, would immediately seek out another product that met these requirements through the use of natural ingredients." He also relies on Mr. Hornbuckles's opinion that "between 43% and 60% of GNI's sales of falsely advertised Violative Products would likely have been captured by ThermoLife."

As found above, Mr. Berger's survey, report, and testimony are not reliable, and Mr. Hornbuckle's report and testimony are not based on sufficient facts or data, not the product of reliable principles and methods, and likely to mislead the jury. Even if it were reasonable to assume that GNI's customers would have made different purchasing decisions if they were told that Novedex XT, Halodrol Liquigels, and Halodrol MT were not DSHEA-compliant, "safe," and "natural," there is no basis for concluding that any specific percentage of them would have purchased TLI's testosterone boosting products.

Mr. Epperson concludes, "As such, of the $17,284,117 in profits GNI earned from the sale of the Violative Products that directly competed with ThermoLife products, lost profits to ThermoLife are reasonably estimated as ranging from $4,682,267 to $6,533,396."

For all of these reasons, Mr. Epperson's opinions regarding disgorgement of GNI's profits and TLI's lost profits are not based on sufficient facts or data, are not the product of reliable principles and methods, and are likely to mislead the jury.

F. Jim Prochnow, GNI's Legal Expert

In his expert report dated May 31, 2013, Mr. Prochnow states that he was engaged by GNI to analyze the allegations of the First Amended Complaint in the context of the DSHEA and the compliance and enforcement actions of the FDA with respect to the dietary supplements about which GNI allegedly made false statements. Mr. Prochnow is

an attorney whose practice focuses on regulatory affairs and litigation with an emphasis on food and drug law and advertising law.

Mr. Prochnow's Expert Report provides only his legal opinions. He opines that the First Amended Complaint "reflects and evidences a misunderstanding of what DSHEA requires of dietary supplement products and those who promote, label and manufacture them." He also opines that the FDA's public safety alert "is an informal unilateral Agency action that does not constitute: (a) an enforcement action necessitating a mandatory product recall, (b) a declaration that the product is an imminent hazard to human health, or (c) a determination that there is a 'reasonable probability' of permanent impairment of body structure or function in those other than 'at risk consumers.'"

Mr. Prochnow states that none of the terms "DSHEA-compliant," "legal," "safe," or "natural" is defined by the FDCA or DSHEA, and he provides legal argument regarding how each term should be construed and applied here. He opines that "the meaning of the term 'DSHEA-Compliant' should be determined from the standpoint of a typical consumer," but has no survey data regarding the standpoint of a typical consumer. Instead, he opines that "'DSHEA-Compliant' means nothing to almost all consumers because they are unaware of what 'DSHEA' means."

Mr. Prochnow's June 24, 2013 Response Report responds to the report of Dr. Sox. Mr. Prochnow disagrees with Dr. Sox's opinions regarding "natural," "safe," and "DSHEA-compliant" by providing legal analysis and argument.

Although expert testimony may embrace an ultimate issue to be decided by the trier of fact, Fed. R. Evid. 704(a), an expert witness may not give an opinion on an ultimate issue of law. *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1016 (9th Cir. 2004). Instructing the jury regarding the applicable law is the exclusive province of the court. *Id.* Moreover, Fed. R. Evid. 702(b) requires that an expert's testimony be based on "sufficient facts or data."

Both Mr. Prochnow's Expert Report and Response Report provide opinions on ultimate issues of law and nothing more. His opinions are not based on facts or data, but rather his legal interpretations. They invade the Court's exclusive province to instruct the jury regarding the applicable law. Therefore, Plaintiff's Daubert Motion to Exclude the Expert Report, Response Report, and Testimony of Jim Prochnow (Doc. 190) will be granted.

G. Stephen Clarke, GNI's Damages Expert

In his expert report dated May 31, 2013, Mr. Clarke states he was engaged by GNI to quantify damages in the form of lost profits from sales of its nutritional supplements following the May 25, 2012 publication of an article titled "Federal Judge allows ThermoLife to take SUPER DUMP on Gaspari." He does not opine regarding damages that may have been caused by TLI's actions prior to May 25, 2012.

During his deposition, Mr. Clarke testified that he was not engaged to determine whether the publication of the article caused damages, but that he assumed causation. However, in a section of his expert report titled "Causation," he states that publication of the May 25, 2012 "SUPER DUMP" article "caused GNI to lose sales."

Mr. Clarke observes that GNI's sales increased every year prior to the posting of the article, whether considered by calendar year or June-May years, and declined following the posting of the article. He also observes that "the period from March to June 2012 was the only time in the company's history that it recorded three consecutive months of decreasing sales," but he does not explain what caused the decrease in sales in the two and a half months before May 25, 2012.

He notes that GNI "weathered the storm" of the December 2007 through June 2009 recession and calculates that GNI's 3-month trailing average sales revenues increased by 175% from $2 million in December 2007 to $5.5 million in June 2009. Although Mr. Clarke does not opine regarding damages caused by TLI's alleged false

disparaging statements made in September 2008 and early 2010, his observations regarding GNI's revenues undermine GNI's claims that those statements caused harm.

Mr. Clarke's qualifications as an expert are not challenged. But his testimony would not help the trier of fact understand the evidence or determine a fact in issue because it is not limited to the particular task he was assigned, *i.e.*, quantifying damages. He observes the correlation between GNI's decline in sales revenues and the date the "SUPER DUMP" article was published and opines that the correlation establishes causation without any hard evidence. This testimony is likely to confuse and mislead the jury.

Moreover, Mr. Clarke's factual observations regarding the decline in GNI's sales revenues the two and a half months before May 25, 2012, suggest something other than the publication of the "SUPER DUMP" article caused GNI's sales to begin to decline. Further, his observations of GNI's strong performance despite the recession suggest that GNI's allegations of damage caused by TLI's misrepresentations in 2008 and early 2010 are unfounded. These observations may be helpful to the trier of fact, but would not serve GNI's purpose in offering Mr. Clarke as an expert.

Therefore, Plaintiff's *Daubert* Motion to Exclude the Expert Report and Testimony of Stephen Clarke (Doc. 205) will be granted.

III. MOTIONS FOR SUMMARY JUDGMENT

A. Legal Standard

Summary judgment is proper if the evidence shows there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party must produce evidence and show there is no genuine issue of material fact. *Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Cos., Inc.*, 210 F.3d 1099, 1102 (9th Cir. 2000). If the burden of persuasion at trial would be on the nonmoving party, the party moving for summary judgment may carry its initial burden of production under Rule 56(c) by producing "evidence negating an essential element of the

nonmoving party's case," or by showing, after suitable discovery, that the "nonmoving party does not have enough evidence of an essential element of its claim or defense to carry its ultimate burden of persuasion at trial." *Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1105-06 (9th Cir. 2000); *High Tech Gays v. Defense Indus. Sec. Clearance Office*, 895 F.2d 563, 574 (9th Cir. 1990).

The party seeking summary judgment bears the initial burden of identifying the basis for its motion and those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which demonstrate the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). When the moving party has carried its burden, the nonmoving party must produce evidence to support its claim or defense by more than simply showing "there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). To defeat a motion for summary judgment, the nonmoving party must show that there are genuine issues of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). A material fact is one that might affect the outcome of the suit under the governing law. *Id.* at 248. A factual issue is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

On summary judgment, the nonmoving party's evidence is presumed true, and all inferences from the evidence are drawn in the light most favorable to the nonmoving party. *Eisenberg v. Ins. Co. of North America*, 815 F.2d 1285, 1289 (9th Cir. 1987); *Baldwin v. Trailer Inns, Inc.*, 266 F.3d 1104, 1117 (9th Cir. 2001). But the evidence presented by the parties must be admissible. LRCiv 56.1(a), (b); see Fed. R. Civ. P. 56(e). Conclusory and speculative testimony in affidavits and moving papers is insufficient to raise genuine issues of fact and to defeat summary judgment. *Thornhill Publ'g Co., Inc. v. GTE Corp.*, 594 F.2d 730, 738 (9th Cir. 1979). "If a party fails to properly support an assertion of fact or fails to properly address another party's assertion

of fact as required by Rule 56(c), the court may . . . consider the fact undisputed for purposes of the motion." Fed. R. Civ. 56(e)(2).

B. Undisputed Material Facts

GNI sold Novedex XT, Halodrol Liquigels, and Halodrol MT as dietary supplements designed to increase testosterone levels. GNI sold SuperPump 250 as a pre-workout dietary supplement to assist in the development of lean body mass. Neither Halodrol MT nor SuperPump 250 has been the subject of a recall.

On January 15, 2010, the FDA issued a press release announcing that MuscleMaster.com, Inc., an unrelated third-party retailer, was conducting a voluntary nationwide recall of 17 dietary supplements, including Novedex XT and Halodrol Liquigels, that were sold between June 1, 2009, and November 17, 2009. The press release states the FDA advised MuscleMaster.com "of its concern that the Recalled Products may contain [] ingredients that are currently classified, or the FDA believes should be classified, as steroids." It further states, "While MuscleMaster.com cannot independently confirm the FDA's concerns that any one or more of the Recalled Products in fact contain these ingredients, MuscleMaster.com is undertaking this voluntary recall out of an abundance of caution and in deference to FDA's stated concerns." The press release states the possible harmful effects of using steroid-containing products include acute liver injury, shrinkage of the testes, male infertility, adverse effects on blood lipid levels, and increased risk of heart attack, stroke, and death.

On October 7, 2010, the FDA issued a press release announcing GNI was conducting a voluntary nationwide recall of Novedex XT, a product marketed as a dietary supplement containing an aromatase inhibitor ("ATD"). The press release states that GNI "is conducting this consumer level recall after being informed by representatives of the [FDA] that 3,17-keto-etiocholetriene does not meet the definition of a dietary ingredient and therefore the product is in violation of provisions of the [FDCA]." The press release also states that GNI discontinued domestic sales of Novedex XT on October

4, 2010. It describes potential adverse effects associated with the use of ATD as "decreased rate of bone maturation and growth, decreased sperm production, infertility, aggressive behavior, adrenal insufficiency, kidney failure, and liver dysfunction." TLI has been aware of GNI's use of ATD since at least February 2006.

Turkesterone is a substance derived from the plant Ajuga Tukestanica that was included in SuperPump 250 since it was first sold. The formulators of SuperPump 250 testified that there was turkesterone in SuperPump 250, although in an amount so small that it may not appear in tests. In January 2009, the formulation of SuperPump 250 was changed from .0005 milligrams of turkesterone per serving to 1 milligram per serving. In June 2006, TLI questioned GNI's ability to obtain turkesterone. TLI claimed to have an exclusive agreement for the sale of turkesterone in the United States during the times that GNI sold turkesterone.

At various times, the labels of Halodrol MT and Halodrol Liquigels listed as an ingredient 3,4 divanillytetrahydrofuran, which is a compound obtained from stinging nettles. The Halodrol MT label indicated that the 3,4 divanillytetrahydrofuran it contained was 95% pure. Although TLI alleges that it is not commercially viable for any dietary supplement manufacturer to use 3,4 divanillytetrahydrofuran that is 95% pure, GNI's suppliers reported that the product they supplied was 95% pure.

Many of the allegedly false advertisments about which TLI complains are internet bulletin board posts on Bodybuilding.com. On September 22, 2008, Mr. Kramer posted on Bodybuilding.com a statement that Mr. Gaspari "was a joke in this industry peddling protein from his garage." Previously, in an interview with Bodybuilding.com in February 2007, Mr. Gaspari stated that in 1999 he began selling product out of his car and used his mother's garage and basement as his warehouse and office. On September 22, 2008, Mr. Kramer also posted that "Gaspari was a joke in this industry," "knows nothing about supplements," and "would be a personal trainer at 24 Hour Fitness" without Bruce Kneller.

TLI's website has a forum moderated by "Truth Speaker." In a series of forum posts beginning in January 2010, TLI discussed a press release by TLI and Anabolic Xtreme regarding "a potential problem with one of AX's ingredients, 3,4 divanillytetrahydrofuran. The press release states that TLI commissioned an independent lab to analyze the purity of the compound marketed as 95% 3,4 divanillytetrahydrofuran, which found that the product had less than 5% purity. The press release also states:

> While confident that the ingredient formerly known as 3,4-D "works," due to the enormous amount of consumer feedback and the Mass-FX University study, the information provided from the results of ThermoLife's independent market analysis of the compound has responsibly led AX to change its labels to identify the material as "a proprietary extract of the Urtica dioca plant" to comply with federal labeling regulations.

In its posts on TLI's website forum, TLI stated that if the ingredient were 95% pure, it would be white or very close to white and this ingredient is a brown powder. TLI further stated, "ALL the material in the market is nothing more than a crude nettle extract and NOT 95% of anything."

On April 6, 2012, TLI, represented as "Truth Speaker," posted a forum message on the TLI website, attaching lab test results conducted on GNI's Vasotropin. The post is titled "GASPARI selling SAW DUST???" The forum message claims that "independent lab test results" indicated that each tablet of Vasotropin contains 0.548 milligrams of nitrates, which TLI contends is ineffective: "A dose that will do NOTHING for anyone expecting a pump but may make Gayspari [*sic*] and the scammers that work for him rich and you a sucker!" GNI alleges that the post falsely suggests that nitrates are the key ingredient in Vasotropin.

C. TLI's Claims

In its First Amended Complaint, TLI alleges that GNI made the following representations and they are false and/or misleading:

1. All of GNI's products are legal, do not contain illegal or banned substances, and are labeled in accordance with federal and state law.

2. Novedex XT is DSHEA-compliant.

3. Novedex XT is naturally occurring.

4. Novedex XT is safe and "the safest."

5. Halodrol Liquigels and Halodrol MT are DSHEA-compliant.

6. Halodrol Liquigels and Halodrol MT are safe.

7. Halodrol Liquigels and Halodrol MT contain 95% 3,4-divanillytetrahydrofuran.

8. SuperPump 250 contains turkesterone.

9. GNI's products contain effective doses.

(Doc. 38.) TLI also alleges claims of common law unfair competition and tortious interference with business and business expectancy. (*Id.*)

1. False Advertising Under 15 U.S.C. § 1125(a)(1)(B)

Under 15 U.S.C. § 1125(a)(1)(B):

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . .
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act.

To succeed on a false advertising claim under 15 U.S.C. § 1125(a)(1)(B), a plaintiff must prove:

> (1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a

> substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the goodwill associated with its products.

Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997) (citations omitted); *accord TrafficSchool.com, Inc., v. Edriver, Inc.*, 653 F.3d 820, 828-29 (9th Cir. 2011).

a. No Private Enforcement of the DSHEA

To prove any of its false advertising claims, TLI must demonstrate that GNI made a false statement of fact about one of GNI's products. It may do so by showing that the statement was literally false or that the statement was literally true but likely to mislead or confuse consumers. GNI contends that TLI is attempting to privately enforce the DSHEA by asking the Court to determine whether certain products are "legal," "DSHEA-compliant," "naturally occurring," and/or "safe" when the FDA has not made such a determination.

Section 337 of the FDCA expressly bars private enforcement of the statute, which includes the DSHEA. 21 U.S.C. § 337(a). "Because the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when [] the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010). Further, "*PhotoMedex* teaches that the Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority." *Pom Wonderful, LLC v. The Coca-Cola Co.*, 679 F.3d 1170, 1176 (9th Cir. 2012). A plaintiff may not sue under the Lanham Act to enforce the FDCA or its regulations because it would undermine congressional intent to limit enforcement of the FDCA to the federal government. *Id.* at 1175-76. A plaintiff may not maintain a Lanham Act claim that would require a court to interpret ambiguous

FDA regulations if the FDA has not done so. *Id.* at 1176. Where the FDA has not concluded that particular conduct violates the FDCA, a Lanham Act claim may not be pursued if the claim would require litigating whether that conduct violates the FDCA. *Id.* However, if an affirmative statement of FDA approval is required before a product can be marketed and no such approval has been granted, a Lanham Act claim could be pursued for injuries suffered by a competitor as a result of the false assertion that FDA approval had been granted. *Photomedex*, 601 F.3d at 924-25.

Dietary supplements are considered "foods" for the purposes of the adulterated food provisions of the FDCA. 21 U.S.C. § 321(ff); *Nutritional Health Alliance v. Food & Drug Admin.*, 318 F.3d 92, 98 n.5 (2d Cir. 2003). The FDCA grants the FDA jurisdiction over dietary supplements similar, but not identical, to its jurisdiction over foods. *Nutritional Health Alliance*, 318 F.3d at 98 n.5. The FDA is authorized to prevent adulterated products from entering the market. *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1035 (10th Cir. 2006). Under the heading "Dietary supplement or ingredient: safety," the FDCA authorizes the FDA to declare that a dietary supplement is "adulterated" if it meets certain criteria, but the FDA bears the burden of proof in seeking to have a dietary supplement declared adulterated. 21 U.S.C. § 342(f)(1). In contrast, the FDCA requires the manufacturer of a drug or device to bear the burden of proving that the drug or device is safe before it may be marketed. *United States v. 5 Unlabeled Boxes*, 572 F.3d 169, 171 n.2 (3d Cir. 2009). Thus, a dietary supplement or ingredient is not determined to be unsafe, not DSHEA-compliant, and/or illegal until the FDA proves and declares the product to be adulterated.

Plainly, judicial determination of the falsity of statements that certain dietary supplements are "legal," "DSHEA-compliant," and/or "safe" without a determination by the FDA would usurp or undermine FDA authority. Therefore, TLI's Counts 1, 2, 4, 5, and 6 are barred by 21 U.S.C. § 337(a).

b. Falsity of GNI's Statements

"To demonstrate falsity within the meaning of the Lanham Act, a plaintiff may show that the statement was literally false, either on its face or by necessary implication, or that the statement was literally true but likely to mislead or confuse consumers." *Southland Sod Farms*, 108 F.3d at 1139. To be actionable under 15 U.S.C. § 1125(a)(1)(B), a false statement must be more than mere puffery:

> "Puffing" is exaggerated advertising, blustering, and boasting upon which no reasonable buyer would rely and is not actionable under § 43(a). While product superiority claims that are vague or highly subjective often amount to nonactionable puffery, misdescriptions of specific or absolute characteristics of a product are actionable.

Id. at 1145 (internal quotation marks and citations omitted). "Thus, a statement that is quantifiable, that makes a claim as to the specific or absolute characteristics of a product, may be an actionable statement of fact while a general, subjective claim about a product is non-actionable puffery." *Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1053 (9th Cir. 2008).

"Absent a clear and unambiguous ruling from a court or agency of competent jurisdiction, statements by laypersons that purport to interpret the meaning of a statute or regulation are opinion statements, and not statements of fact." *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 731 (9th Cir. 1999). And statements of opinion are generally not actionable under 15 U.S.C. § 1125(a)(1)(B). *Id.*

Because a dietary supplement or ingredient is not determined to be unsafe, not DSHEA-compliant, and/or illegal until the FDA proves and declares the product to be adulterated, GNI's assertions to that effect were not false at the time they were made. Therefore, TLI's Counts 1, 2, 4, 5, and 6 fail.

TLI's Count 3 alleges that GNI falsely advertised that Novedex XT "is the safest way to naturally cause positive anabolic effect," is a "natural vehicle," contains "naturally occurring anti-aromatase inhibiting compounds," and "has been shown to increase natural

production." TLI also alleges that GNI stated, "When was the last time you could get these kind of effects from a safe, naturally occurring combination of compounds? The answer is never." TLI further alleges that GNI falsely advertised that the active ingredients in Novedex XT "are naturally occurring and are found in normal foodstuffs." The parties dispute whether an ingredient in Novedex can be considered "natural" or "naturally occurring" because the ingredient can be synthesized from naturally occurring material. Without a standard for determining "natural" or "naturally occurring," and no determination by the FDA at the time GNI's statements were made, these statements represent opinions, not "a claim as to the specific or absolute characteristics of a product." Therefore, TLI's claim 3 fails.

TLI's Count 7 refers to both Halodrol Liquigels and Halodrol MT, but the label for Halodrol Liquigels listed 3,4 divanillytetrahydrofuran without claiming 95% purity. Therefore, TLI's Count 7 fails in part.

There is no dispute that SuperPump 250 contained some turkesterone. Therefore, TLI's Count 8 fails.

TLI's Count 9 alleges that GNI falsely advertised its products as containing effective doses. Specifically, TLI alleges that GNI stated in a marketing video uploaded to YouTube.com that its products use ingredients "in doses validated by those [clinical] studies" and that the statement is false because SuperPump 250 allegedly contains little or no turkesterone. However, even if SuperPump 250 contained no turkesterone, TLI has not proven GNI's general statement regarding "effective doses" of unnamed ingredients to be false. Therefore, Count 9 fails.

c. Materiality

Although TLI's expert, James T. Berger, opined that "users of testosterone boosting supplements are very careful and mindful of the products they use," as found above, his survey, report, and testimony are not reliable. But even if Mr. Berger's opinions are considered, TLI has not produced evidence sufficient to show a genuine

issue of material fact regarding whether any of GNI's allegedly false statements "actually deceived or has the tendency to deceive a substantial segment of its audience" and "the deception is material, in that it is likely to influence the purchasing decision." *See Southland Sod Farms*, 108 F.3d at 1139.

d. Injury

GNI contends that TLI has failed to establish actual harm and, even if it had, it cannot substantiate the amount of harm. Under 15 U.S.C. 1125(a)(1)(B), a plaintiff must show that it "has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the goodwill associated with its products." *Southland Sod Farms*, 108 F.3d at 1139. If a plaintiff claims damages in the form of lost profits, it cannot establish causation unless it can show that the false statement caused damage by influencing purchasing decisions. *William H. Morris Co. v. Group W, Inc.*, 66 F.3d 255, 257 (9th Cir. 1995).

TLI reasons that steroids are not safe, legal, natural, or DSHEA-compliant, but effective; therefore, "when given the choice between two products that advertising suggests are interchangeable, consumers chose the product that was more effective—but this was only possible because GNI never told consumers the illegal and dangerous nature of its products." But consumers were given the choice among numerous products, not just two. TLI has not shown that consumers would have chosen TLI's products instead of GNI's products, but for GNI's allegedly false further advertising. Further, TLI's argument suggests that consumers purchased GNI's products because they were more effective, not because they were advertised as safe, legal, natural, and DSHEA-compliant. Moreover, as concluded above, GNI's statements have not been shown to have been false at the time they were made.

For reasons explained above, the report and testimony of TLI's market expert, Ryan Hornbuckle, and the lost profit analysis of TLI's damages expert, Ron Epperson, will be excluded. However, even if those expert opinions are considered, TLI has not

shown a genuine issue of material fact regarding actual harm suffered by TLI caused by GNI's allegedly false statements.

e. Statute of Limitations/Laches (Counts 1, 2, 3, 4, 8, and 9)

GNI contends that the three-year statute of limitations bars TLI's Counts 1-4 and 8-9, because it knew or should have known before May 16, 2008, about GNI's allegedly false advertisement of its products as safe, legal, natural, and DSHEA-compliant and containing turkesterone. Regarding Counts 1-4, GNI points to three email exchanges as evidence TLI knew or should have known of the basis on which it now says that GNI's advertisement of Novedex XT was false. In a February 2006 email exchange, TLI questioned an ingredient supplier regarding whether variants of ATD with ethyl carbonate or THP ether were "naturally occurring" and how either variant would compare to pure ATD. The supplier responded that neither variant was "naturally occurring." But Novedex XT did not include either variant of ATD.

In a July 2006 email exchange, the supplier stated that ATD is "100% compliant" and "found naturally as a fermented cholanolic acid by-product in bovine intestines," such as those used to make sausage casings, and that he had provided the same information to GNI. The supplier also stated that ATD is safe, but that it is not easy to prove safety to the FDA. In a February 2007 email exchange, TLI indicated surprise that GNI's notice to the FDA about new dietary ingredients ("NDI") had passed, with the comment "something does not sound right?" The supplier responded that an NDI did not need approval before a product could be sold and also that "we have evidence ATD is in the food chain—that makes it DSHEA exempt anyhow." None of these emails show that TLI knew or had reason to further investigate in 2006 or 2007 whether Novedex XT, which contained ATD, was DSHEA-compliant, naturally occurring, or safe.

Regarding Counts 8 and 9, GNI points to an email showing that as early as June 2006, TLI knew that GNI listed turkesterone as an ingredient of SuperPump 250 and "was actually very curious" as to GNI's source. The email states that "Turk is next to

impossible to source in quantity," but does not state that GNI could not have obtained it. GNI reasons that TLI should have known that GNI was making "false claims" if TLI's claim that it had the exclusive agreement for the sale of turkesterone in the United States was true. But the context suggests that TLI's attention was focused on whether its alleged exclusivity agreement was being violated or circumvented rather than whether SuperPump 250 contained a testable amount of turkesterone.

Therefore, on the evidence submitted, it cannot be found as a matter of law that Counts 1-4 and 8-9 are barred by the statute of limitations.

GNI further contends that laches bars suit for all similar instances of false advertising, even those within the limitations period, because the lawsuit was filed for false advertising that first occurred outside of the limitations period. Laches is a valid defense to Lanham Act claims, including those for false advertising. *Jarrow Formulas, Inc. v. Nutrition Now, Inc.*, 304 F.3d 829, 835 (9th Cir. 2002). Section 43(a) borrows a state limitations period as a statute of limitations period, which here is three years. *Id.* at 836. "[I]f a § 43(a) claim is filed within the analogous state limitations period, the strong presumption is that laches is inapplicable; if the claim is filed after the analogous limitations period has expired, the presumption is that laches is a bar to suit." *Id.* at 837. "For purposes of laches, the limitations period may expire even though part of the defendant's conduct occurred within the limitations period." *Id.* at 838. Thus, on the evidence submitted for summary judgment, the strong presumption here is that laches is not a bar to suit.

As the party asserting laches, GNI must show that (1) TLI's delay in filing suit was unreasonable and (2) GNI would suffer prejudice caused by the delay if the suit were to continue. *See id.* The length of the delay is measured from the time the plaintiff knew or should have known about its potential cause of action. *Id.* The reasonableness of the delay is considered in comparison to the length of the analogous state limitations period. *Id.* Whether the plaintiff provides a legitimate excuse for the delay also is considered.

Id. Here, if GNI had shown that TLI knew or had reason to know about its potential false advertising claims regarding Novedex XT and SuperPump 250 in 2006, the delay would have been two years beyond the analogous state limitations period. But TLI asserts that it did not know that SuperPump 250 did not contain turkesterone or that it contained an ineffective amount of turkesterone until it first tested SuperPump 250 in August 2008, and GNI has not shown otherwise. Regarding Novedex XT, the FDA issued a Safety Alert in September 2010, and GNI recalled the product in October 2010. Before that, GNI has shown only two emails questioning whether ATD was safe, natural, legal, and DSHEA-compliant that received assurances from the supplier that it was.

Therefore, on the evidence submitted, it cannot be found as a matter of law that Counts 1-4 and 8-9 are barred by laches.

2. Common Law Unfair Competition

In its response to GNI's motion for summary judgment, TLI did not defend its Count 10 for common law unfair competition, which alleges that GNI falsely marketed its products as DSHEA-compliant. Its lack of response may be deemed a consent to the granting of the motion regarding Count 10. LRCiv 7.2(i). Moreover, Count 10 fails on the merits because § 337 of the FDCA "limits the ability of a private plaintiff to pursue claims under state law theories where such claims collide with the exclusive enforcement power of the federal government." *Photomedex*, 601 F.3d at 924.

3. Tortious Interference with Business and Business Expectancy

TLI's Count 11 alleges that GNI improperly interfered with TLI's prospective and expected business or economic relationship by improperly demanding that American Media, Inc., not allow TLI to exhibit at the Mr. Olympia Weekend Expo on September 25-26, 2009, and by threatening to pull its advertising from American Media, Inc.'s publications if TLI was allowed to attend the Mr. Olympia Weekend Expo. On May 16, 2012, Count 11 was dismissed to the extent TLI alleges interference with business

expectancy of relationships with consumers at the Mr. Olympia Weekend Expo. (Doc. 46.)

Count 11 also alleges that TLI suffered damages because it had already made arrangements to attend the event, including purchasing plane tickets, making hotel reservations, and planning its exhibition for the event. However, TLI representatives attended the event; they just were not permitted to exhibit. Moreover, some of TLI's alleged expenses were incurred after it was notified of American Media, Inc.'s decision. TLI has not shown that it incurred any expenses resulting from being denied permission to exhibit that it could not have avoided.

Finally, TLI contends that denial of permission to exhibit caused it to lose a potential business relationship. Mr. Kramer testified that he thought TLI had preliminary plans to meet with a dietary supplement distributor at the Mr. Olympia Weekend Expo, but the distributor "discounted" him after he was unable to exhibit at the expo. But the mere hope of a prospective business relationship is insufficient to establish tortious interference with a business expectancy. *Dube v. Likins*, 216 Ariz. 406, 414, 167 P.3d 93, 101 (Ct. App. 2007).

Therefore, Gaspari Nutrition, Inc.'s Motion for Summary Judgment (Doc. 203) will be granted.

D. GNI's Counterclaim

In its Counterclaim (Doc. 47), GNI alleges that TLI made false disparaging statements about GNI and its products in September 2008, early 2010, and April-May 2012 on Internet message boards. In briefing, the parties have addressed the alleged misrepresentations as follows:

1. SuperPump 250 does not contain the ingredient turkesterone.

2. SuperPump 250 is not effective.

3. Vasotropin is "ineffective" because it contains less than 1 mg of nitrates per tablet.

4. Halodrol is "ineffective" because it does not contain 95% 3,4 divanillytetrahydrofuran.

5. Mr. Gaspari was a joke in the industry peddling protein from his garage.

6. Mr. Gaspari "knows nothing about supplements."

7. Mr. Gaspari "would be a personal trainer at 24 Hour Fitness" if not for GNI formulator Bruce Kneller.

8. Mr. Gaspari is a "counterfeiter."

9. GNI uses expired ingredients in its products.

10. Novedex XT and Halodrol were "spiked" with illegal steroids.

11. ThermoLife's complaint "reads like a criminal indictment."

12. GNI's recently released products are poorly formulated and pixie dusted.

13. GNI will be ordered to turn over all documents related to advertising for SuperPump 250, Halodrol, and Novedex XT.

14. GNI will be required to produce all documents sent to retailers claiming Halodrol and Novedex XT were natural, safe, and DSHEA-compliant.

15. GNI will be required to disclose all gross sales of Halodrol, Novedex XT, and SuperPump 250.

16. GNI's failure to disclose information could result in contempt sanctions and criminal charges.

17. A substantial judgment in this case could put GNI out of business and bankrupt Mr. Gaspari.

18. Federal law provides that if and when GNI is found liable, the court can award treble damages equal to three times the profit GNI earned.

19. The law clearly states that Mr. Gaspari is not entitled to any profit he made from selling these products.

20. GNI is declining in the rankings.

1. False Designations of Origin, False Descriptions, False Advertising, and Unfair Competition (15 U.S.C. § 1125(a))

GNI alleges that TLI's publication of false disparaging statements about GNI and its products constitutes unfair competition, false advertising, false designation of origin, and/or false description under 15 U.S.C. § 1125(a). Again, to succeed on a false advertising claim under 15 U.S.C. § 1125(a)(1)(B), a plaintiff must prove:

> (1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the goodwill associated with its products.

Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997) (citations omitted).

TLI asserts that GNI's characterizations of some of TLI's statements are not factually accurate, other statements are not literally false, and others are non-actionable opinions and predictions about future events. GNI responds that, when interpreted in context, TLI's statements mean much more than the literal words. However, even when read in context, the statements allegedly made by or on behalf of TLI are misstated and/or they are opinions, predictions, or not false.

Further, in its reply in support of its motion for summary judgment, GNI asserts that comments on a general informational message board do not constitute actionable commercial advertisements and that TLI does not show that the posts were disseminated to the relevant purchasing public or that it lost a single customer as a result. Yet all of the statements that GNI alleges were false and made by TLI (or its agents) were made on Internet message boards and GNI does not show that the posts were disseminated to the relevant purchasing public or that it lost a single customer as a result.

Moreover, to show damages, GNI relies entirely on the expert report and testimony of its damages expert, Stephen Clarke, which has been excluded entirely. Even if GNI's statements were false and more than opinions, predictions, and puffery, GNI has failed to show any of the statements actually deceived or had the tendency to deceive a substantial segment of its audience, the deception was likely to influence the purchasing decision, and GNI has been or is likely to be injured as a result of the false statement. Therefore, TLI will be granted summary judgment on GNI's Count 1.

2. Common Law Unfair Competition

GNI's Count 2 alleges that TLI represented that GNI's products were illegal, mislabeled, dangerous, and ineffective without a basis in fact sufficient to validate those claims, and that TLI's "representations constitute false advertising, which is actionable as unfair competition under Arizona common law." As concluded above, the alleged statements do not constitute actionable false advertising, and GNI has not shown the statements caused GNI injury.

Therefore, TLI will be granted summary judgment on GNI's Count 2.

3. Trade Disparagement

In its Count 3, GNI alleges TLI published a series of statements on its forums and in other electronic body building forums that are false, misleading, defamatory, and made with reckless disregard as to the truth or falsity of those statements. Count 3 alleges that, as a result, GNI's name has been disparaged and its goodwill injured. GNI concedes, however, that its damages expert, Mr. Clarke, did not expressly opine regarding the loss of goodwill. Moreover, Mr. Clarke's opinion is not admissible. GNI has not shown it suffered any injury as a result of TLI's allegedly disparaging statements.

Therefore, TLI will be granted summary judgment on GNI's Count 3.

E. TLI's Renewed Request for Dismissal as a Spoliation Sanction

In its motion for summary judgment, TLI renews its previous request for dismissal as a spoliation sanction. (Doc. 206 at 27-30.) Although TLI's motion for summary

judgment on GNI's Counterclaim will be granted, TLI's request for dismissal as a spoliation sanction will be denied for reasons explained below.

IV. ADDITIONAL MOTIONS

A. Motion for Spoliation Sanctions (Doc. 216) and Motion to Strike Declaration (Doc. 267)

In addition to requesting dismissal for spoliation in its motion for summary judgment (Doc. 206), on September 3, 2013, TLI requested that the Court immediately impose spoliation sanctions against GNI by imposing default judgment in TLI's favor on TLI's claims, dismissing GNI's counterclaim with prejudice, and ordering GNI to bear TLI's fees and costs. (Doc. 216.) On September 20, 2013, GNI filed its response to the motion for sanctions, and on September 30, 2013, TLI filed a reply with four exhibits, one of which was the Declaration of Ted Willard. (Docs. 246, 264.) On October 3, 2013, GNI moved to strike the Declaration of Ted Willard and portions of the reply that rely on the Declaration as exceeding the proper scope of a reply brief. (Doc. 267.)

Under its inherent power and Fed. R. Civ. P. 37(b), the Court has discretion to sanction a party responsible for the spoliation of evidence. *Leon v. IDX Sys. Corp.*, 464 F.3d 951, 958 (9th Cir. 2006) (finding that willful destruction of electronic files constituted spoliation). Before imposing the "harsh sanction" of dismissal, however, the district court should consider "(1) the public's interest in expeditious resolution of litigation; (2) the court's need to manage its dockets; (3) the risk of prejudice to the party seeking sanctions; (4) the public policy favoring disposition of cases on their merits; and (5) the availability of less drastic sanctions." *Id.* (quoting *Anheuser-Busch, Inc. v. Natural Beverage Distribs.*, 69 F.3d 337, 348 (9th Cir. 1995)). Before ordering outright dismissal, the court must make a finding of willfulness, fault, or bad faith and must consider less severe alternatives. *Id.* "A party's destruction of evidence qualifies as willful spoliation if the party has some notice that the documents were *potentially* relevant to the litigation before they were destroyed." *Id.* at 959.

TLI contends that the hard drive of a computer used by Mr. Gaspari from May 11, 2012, through July 22, 2013, was "scrubbed" to permanently remove deleted files. An expert for each party has opined regarding whether what remains in the hard drive implies that the hard drive was scrubbed. The evidence is too speculative for the Court to conclusively find willfulness, fault, or bad faith. Moreover, the risk of prejudice to TLI has been mitigated by TLI obtaining the documents and emails it expected to find on Mr. Gaspari's computer from other sources.

Therefore, TLI's motion for spoliation sanctions will be denied, and the motion to strike is moot.

B. TLI's Motion for Case-Dispositive Sanctions Due to Defendant's Failure to Produce Relevant Documents in Discovery (Doc. 355)

TLI also seeks dismissal of GNI's Counterclaim and default judgment on TLI's First Amended Complaint under Fed. R. Civ. P. 37(b) and (d) because when GNI was ordered by the Discovery Master to permit six of its hard drives to be imaged and searched by TLI's third-party vendor, the search generated "hundreds of highly relevant documents" that TLI contends should have been disclosed and produced by GNI two years earlier. TLI further contends that the untimely production revealed that GNI had in its possession "thousands of relevant documents," several of which are "smoking gun documents." TLI asserts injury because the documents were produced too late for use during depositions of witnesses who cannot be compelled to testify at trial.

GNI responds that previous rulings by the Court and the Discovery Master have cured any perceived prejudice. Specifically, the parties were granted leave to file supplemental briefs as to all pending motions addressing the late-produced discovery. (Doc. 254.) In its supplemental brief, TLI asserts that the late-produced discovery shows that "GNI knew all along that its advertising was false on its face." For example, it cites an August 2009 email between two GNI employees discussing an alternative ingredient for Novedex to replace ATD because it would be "a much better ingredient to defend."

Contrary to TLI's assertion, the email does not show that "ATD was not legal or DSHEA-compliant in December 2006." Similarly, an email in 2008 questioning whether ATD exists in the intestine of animals because a professor thought it did not, but "was not 100% sure about this," does not prove that ATD is not "naturally occurring" and that, if it is not, GNI knew that as a fact in 2008. An October 14, 2009 email in which a supplier stated that he could not confirm the purity of 3,4-divanillytetrahydrofuran as 95%, but was able to confirm the range of purity as 65-95%, is not "a smoking gun." Although some of the email exchanges cast suspicion on GNI, they do not support the extent of TLI's conclusions.

Some of the documents GNI failed to initially produce were relevant to the subject matter of this action and not unduly burdensome to produce. However, the subsequently ordered search of the six computer hard drives yielded many more documents than necessary or helpful to determination of the parties' claims. Prejudice to TLI has been mitigated by supplemental briefing, and TLI has not shown that production of the "smoking gun documents" before depositions would have altered the outcome of this litigation.

Considering the risk of prejudice to the party seeking sanctions and the public policy favoring disposition of cases on their merits, the Court declines to impose the case-dispositive sanctions sought by TLI.

C. GNI's Motion in Limine to Exclude Certain FDA Statements (Doc. 319)

GNI moves to exclude at trial preliminary and informal statements made by the FDA about GNI's products in anticipation that TLI will rely on them to establish GNI's liability for false advertising. Because this action is entirely resolved by summary judgment, GNI's motion in limine is moot.

IT IS THEREFORE ORDERED that:

1. Gaspari Nutrition, Inc.'s Motion to Exclude Portions of Response Report and Areas of Testimony of Dr. Thomas Sox (Doc. 178) is **granted**.

2. Gaspari Nutrition, Inc.'s Motion to Exclude Survey, Report and Testimony of James T. Berger (Doc. 181) is **granted**.

3. Plaintiff's *Daubert* Motion to Exclude the Expert Report, Response Report, and Testimony of Jim Prochnow (Doc. 190) is **granted**.

4. Gaspari Nutrition, Inc.'s Motion to Exclude Certain Testimony and Opinions of Ron Epperson (Doc. 201) is **granted**.

5. Gaspari Nutrition, Inc.'s Motion to Exclude Report and Testimony of Ryan Hornbuckle (Doc. 202) is **granted**.

6. Plaintiff's *Daubert* Motion to Exclude the Expert Report and Testimony of Stephen Clarke (Doc. 205) is **granted**.

7. Gaspari Nutrition, Inc.'s Motion for Summary Judgment (Doc. 203) is **granted**.

8. Motion for Summary Judgment on Gaspari Nutrition Inc.'s Counterclaims (Doc. 206) by ThermoLife International, LLC is **granted**.

9. Plaintiff's Motion for Sanctions Due to Gaspari Nutrition Inc.'s Intentional Destruction of Evidence and GNI's Efforts to Conceal Its Wrongful Conduct (Doc. 216) is **denied**.

10. Motion to Strike Declaration of Ted Willard and Portions of Reply That Rely on the Willard Declaration (Doc. 267) by Gaspari Nutrition, Inc., is **denied as moot**.

11. ThermoLife's Motion for Sanctions Due to Defendant's Failure to Produce Relevant Documents in Discovery (Doc. 355) is **denied**.

12. Gaspari Nutrition, Inc.'s *Motion in Limine* No. 1 to Exclude Certain FDA Statements (Doc. 319) is **denied as moot**.

IT IS FURTHER ORDERED that the Clerk enter judgment against Plaintiff ThermoLife International, LLC, on its complaint and in favor of Defendant Gaspari Nutrition, Inc., and that Plaintiff take nothing.

IT IS FURTHER ORDERED that the Clerk enter judgment against Counterclaimant Gaspari Nutrition, Inc., on its counterclaim and in favor of Counterdefendant ThermoLife International, LLC, and that Counterclaimant take nothing.

The Clerk shall terminate this case.

Dated this 10th day of January, 2014.

Neil V. Wake
United States District Judge