U.S. District Court California Northern District (Oakland) CIVIL DOCKET FOR CASE #: 4:14-cv-05682-JSW

Ryan et al v. Gencor Nutrients, Inc. et al Assigned to: Hon. Jeffrey S. White

Demand: \$5,001,000

Cause: 18:1961 Racketeering (RICO) Act

Date Filed: 12/31/2014 Jury Demand: Plaintiff

Nature of Suit: 470 Racketeer/Corrupt

Organization

Jurisdiction: Federal Question

Plaintiff

Michael Ryan represented by Barry R. Himmelstein

HIMMELSTEIN LAW NETWORK

2000 Powell St. Suite 1605

Emeryville, CA 94608-1861

(510) 450-0782 Fax: (510) 924-0403

Email: barry@himmellaw.com *ATTORNEY TO BE NOTICED*

Plaintiff

Marco Garza represented by Barry R. Himmelstein

(See above for address)

ATTORNEY TO BE NOTICED

Plaintiff

Michael Aguero represented by Barry R. Himmelstein

(See above for address)

ATTORNEY TO BE NOTICED

Plaintiff

Odell Cowans represented by Barry R. Himmelstein

(See above for address)

ATTORNEY TO BE NOTICED

Plaintiff

Brett Erion represented by Barry R. Himmelstein

(See above for address)

ATTORNEY TO BE NOTICED

Plaintiff

Russ Ruhnke represented by Barry R. Himmelstein

(See above for address)

ATTORNEY TO BE NOTICED

Plaintiff

Thomas Korves represented by Barry R. Himmelstein

(See above for address)

ATTORNEY TO BE NOTICED

Plaintiff

Luis Flores represented by Barry R. Himmelstein

(See above for address)

ATTORNEY TO BE NOTICED

Plaintiff

Steven Berger represented by Barry R. Himmelstein

(See above for address)

ATTORNEY TO BE NOTICED

Plaintiff

Eligio Torres represented by Barry R. Himmelstein

(See above for address)

ATTORNEY TO BE NOTICED

Plaintiff

Robert Baker represented by Barry R. Himmelstein

(See above for address)

ATTORNEY TO BE NOTICED

V.

Defendant

Gencor Nutrients, Inc.

Defendant

GE Nutrients, Inc.

Defendant

Jith Veeravalli

Defendant

General Nutrition Corporation

Defendant

GNC Corporation

Defendant

General Nutrition Centers, Inc.

Defendant

S&G Properties, LLC

Defendant

Direct Digital LLC

Defendant

Truderma, LLC

Defendant

Force Factor LLC

Defendant

NAC Marketing Company, LLC

Defendant

Kingfisher Media, LLC

Defendant

Dreambrands, Inc.

Defendant

Pharmafreak Holdings Inc.

Defendant

NDS Nutrition Products, Inc.

Defendant

Medical Research Institute, Inc.

Defendant

Prevention, LLC

Defendant

Premium Nutraceuticals, LLC

Date Filed	#	Docket Text
12/31/2014	1	COMPLAINT against All Defendants (Filing fee \$ 400, receipt number 0971-9179150.). Filed byRobert Baker, Thomas Korves, Marco Garza, Michael Ryan, Russ Ruhnke, Michael Aguero, Steven Berger, Luis Flores, Odell Cowans, Eligio Torres, Brett Erion. (Attachments: # 1 Exhibit Part 1, # 2 Exhibit Part 2, # 3 Exhibit Part 3, # 4 Exhibit

		Part 4, # 5 Exhibit Part 5, # 6 Exhibit Part 6, # 7 Exhibit Part 7, # 8 Exhibit Part 8, # 9 Exhibit Part 9, # 10 Exhibit Part 10, # 11 Exhibit Part 11, # 12 Exhibit Part 12, # 13 Exhibit Part 13, # 14 Exhibit Part 14, # 15 Exhibit Part 15, # 16 Exhibit Part 16, # 17 Exhibit Part 17, # 18 Exhibit Part 18, # 19 Exhibit Part 19, # 20 Exhibit Part 20, # 21 Exhibit Part 21, # 22 Exhibit Part 22, # 23 Exhibit Part 23, # 24 Exhibit Part 24, # 25 Exhibit Part 25, # 26 Exhibit Part 26, # 27 Civil Cover Sheet)(Himmelstein, Barry) (Filed on 12/31/2014) (Entered: 12/31/2014)	
12/31/2014	2	Proposed Summons. (Himmelstein, Barry) (Filed on 12/31/2014) (Entered: 12/31/2014)	
01/02/2015	3	Case assigned to Magistrate Judge Nandor J. Vadas. Counsel for plaintiff or the removing party is responsible for serving the Complaint or Notice of Removal, Summons and the assigned judge's standing orders and all other new case documents upon the opposing parties. For information, visit <i>E-Filing A New Civil Case</i> at http://cand.uscourts.gov/ecf/caseopening. Standing orders can be downloaded from the court's web page at www.cand.uscourts.gov/judges. Upon receipt, the summons will be issued and returned electronically. Counsel is required to send chambers a copy of the initiating documents pursuant to L.R. 5-1(e)(7). A scheduling order will be sent by Notice of Electronic Filing	
01/02/2015	4	(NEF) within two business days. (cjlS, COURT STAFF) (Filed on 1/2/2015) (Entered: 01/02/2015) CONSENT/DECLINATION to Proceed Before a US Magistrate Judge by Michael Aguero, Robert Baker, Steven Berger, Odell Cowans, Brett Erion, Luis Flores, Marco Garza, Thomas Korves, Russ Ruhnke, Michael Ryan, Eligio Torres (Himmelstein, Barry) (Filed on 1/2/2015) (Entered: 01/02/2015)	
01/02/2015	<u>5</u>	Summons Issued as to All Defendants. (msr, COURT STAFF) (Filed on 1/2/2015) Modified on 1/2/2015 (msr, COURT STAFF). (Entered: 01/02/2015)	
01/05/2015	6	CLERK'S NOTICE OF IMPENDING REASSIGNMENT TO A U.S. DISTRICT COURT JUDGE: The Clerk of this Court will now randomly reassign this case to a District Judge because either (1) a party has not consented to the jurisdiction of a Magistrate Judge, or (2) time is of the essence in deciding a pending judicial action for which the necessary consents to Magistrate Judge jurisdiction have not been secured. You will be informed by separate notice of the district judge to whom this case is reassigned. ALL HEARING DATES PRESENTLY SCHEDULED BEFORE THE CURRENT MAGISTRATE JUDGE ARE VACATED AND SHOULD BE RENOTICED FOR HEARING BEFORE THE JUDGE TO WHOM THIS CASE IS REASSIGNED. This is a text only docket entry; there is no document associated with this notice. (glm, COURT STAFF) (Filed on 1/5/2015) (Entered: 01/05/2015)	
01/06/2015	7	ORDER REASSIGNING CASE. Case reassigned to Judge Hon. Jeffrey S. White for all further proceedings. Magistrate Judge Nandor J. Vadas no longer assigned to the case. Signed by Executive Committee on 1/6/15. (sv, COURT STAFF) (Filed on 1/6/2015) (Entered: 01/06/2015)	

01/06/2015	8	Certificate of Interested Entities by Michael Aguero, Robert Baker, Steven Berger, Odell Cowans, Brett Erion, Luis Flores, Marco Garza, Thomas Korves, Russ Ruhnke, Michael Ryan, Eligio Torres (Himmelstein, Barry) (Filed on 1/6/2015) (Entered: 01/06/2015)
01/06/2015	9	NOTICE of Voluntary Dismissal <i>of Defendant Medical Research Institute, Inc.</i> by Michael Aguero, Robert Baker, Steven Berger, Odell Cowans, Brett Erion, Luis Flores, Marco Garza, Thomas Korves, Russ Ruhnke, Michael Ryan, Eligio Torres (Himmelstein, Barry) (Filed on 1/6/2015) (Entered: 01/06/2015)

Barry Himmelstein (SBN 157736) barry@himmellaw.com 2 HIMMELSTEIN LAW NETWORK 2000 Powell St., Suite 1605 3 Emeryville, CA 94608-1861 Telephone: (510) 450-0782 4 Facsimile: (510) 924-0403 5 Attorney for Plaintiffs 6 7 8 UNITED STATES DISTRICT COURT 9 NORTHERN DISTRICT OF CALIFORNIA 10 11 MICHAEL RYAN, MARCO GARZA, Case No.: MICHAEL AGUERO, ODELL COWÂNS, BRETT ERION, RUSS RUHNKE, THOMAS) 12 **COMPLAINT FOR** KORVES, LUIŚ FLORES, STEVÉN VIOLATIONS OF RACKETEER BERGER, ELIGIO TORRES, and ROBERT 13 INFLUENCED AND CORRUPT ORGANIZATIONS ACT; VIOLATIONS BAKER, on behalf of themselves and all 14 others similarly situated, OF CONSUMER LEGAL REMEDIES ACT; VIOLATIONS OF UNFAIR Plaintiffs. 15 **COMPETITION LAW; VIOLATIONS OF** FALSE ADVERTISING LAW; BREACH V. 16 OF EXPRESS WARRANTY; BREACH OF IMPLIED WARRANTY OF 17 GENCOR NUTRIENTS, INC.; GE MERCHANTABILITY; BREACH OF NUTRIENTS, INC.; JITH VEERAVALLI; GENERAL NUTRITION CORPORATION; IMPLIED WARRANTÝ OF FITNESS 18 FOR A PARTICULAR PURPOSE: GNC CORPORATION; GENERAL FRAUD; NEGLIGENT NUTRITION CENTERS, INC.; S&G MISREPRESENTATION; 19 PROPERTIES, LLC; DIRECT DIGITAL RESTITUTION; VIOLATIONS OF 20 LLC; TRUDERMA, LLC; FORCE FACTOR PENNSYLVANIA UNFAIR TRADE LLC; NAC MARKÉTING COMPANY, LLC;) PRACTICES AND CONSUMER KINGFISHER MEDIA, LLC PROTECTION LAW; VIOLATIONS OF 21 DREAMBRANDS, INC.; PHARMAFREAK HOLDINGS INC.; NDS NUTRITION PRODUCTS, INC.; MEDICAL RESEARCH INSTITUTE, INC.; PREVENTION, LLC; ARIZONA CONSUMER FRAUD ACT 22 **CLASS ACTION** 23 **DEMAND FOR JURY TRIAL** PREMIUM NUTRACEUTICALS, LLC; and DOES 1-100, 24 Defendants. 25 26 27 28

 Plaintiffs MICHAEL RYAN, MARCO GARZA, MICHAEL AGUERO, ODELL COWANS, BRETT ERION, RUSS RUHNKE, THOMAS KORVES, STEVEN BERGER, ELIGIO TORRES, and ROBERT BAKER, on behalf of themselves and all others similarly situated, allege as follows:

SUMMARY OF ACTION

- 1. Defendants manufacture, market, and sell Testofen or nutritional supplements containing Testofen, an extract of the herb fenugreek. Defendants advertise and market these products as "testosterone boosters," representing that Testofen has been "clinically proven" to increase free testosterone levels. These representations are false, based on universally-accepted principles of statistical analysis that have been adopted by the regulatory bodies of every "first world" country, including the United States.
- 2. Plaintiffs and the other members of the class, who purchased these products based on these false representations, are entitled to get their money back. Treble and punitive damages should be also assessed against defendants, who have sold or continue to sell these products as clinically proven testosterone boosters despite knowledge of the falsity of these representations.
- 3. GNC provides the exclusive "launch" platform for a steady stream of new "testosterone boosters," including Nugenix, Troxyphen, and High T products, giving GNC 100% of the revenue from the retail sales of these products. As both GNC and the manufacturers acknowledge, GNC uses its market dominance and influence with its customers to quickly drive sales of these products to levels far beyond what the manufacturers could otherwise achieve.
- 4. The manufacturers then introduce "new" and purportedly improved versions of each product, and GNC dubs each successive version as the "Newest Latest Greatest," creating an ever-growing product category, occupying ever-growing shelf space, and bringing ever-growing revenues and profits to GNC and its associates in the RICO "Testofenterprise."

JURISDICTION

- 5. This Court has original jurisdiction over this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), in that members of the proposed plaintiff class are citizens of a State different from one or more defendants, and the amount in controversy exceeds the sum of \$5,000,000.
- 6. Pursuant to 18 U.S.C. § 1964 and 28 U.S.C. § 1331, this Court also has original jurisdiction over Plaintiffs' claims for violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). Pursuant to 28 U.S.C. § 1367, this Court also has supplemental jurisdiction over Plaintiffs' state law claims, which are so related to Plaintiffs' RICO claims that they form part of the same case or controversy.

VENUE

7. Venue in this district is proper pursuant to 28 U.S.C. § 1391(b)(2), because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this district.

INTRADISTRICT ASSIGNMENT

8. Pursuant to Civil L.R. 3-2(c), assignment to the San Francisco Division or the Oakland Division is proper, because a substantial part of the events or omissions giving rise to Plaintiff Ryan's claims occurred in Lake County, California.

PARTIES

I. Plaintiffs

- 9. Plaintiff MICHAEL RYAN ("Ryan") is an individual residing in Lake County, California.
- 10. Plaintiff MARCO GARZA ("Garza") is an individual residing in Santa Clara County, California.
- 11. Plaintiff MICHAEL AGUERO ("Aguero") is an individual residing in San Bernardino County, California.

- 12. Plaintiff ODELL COWANS ("Cowans") is an individual residing in Fresno County, California.
- 13. Plaintiff BRETT ERION ("Erion") is an individual residing in Butte County, California.
- 14. Plaintiff RUSS RUHNKE ("Ruhnke") is an individual residing in Orange County, California.
- 15. Plaintiff THOMAS KORVES ("Korves") is an individual residing in Sacramento County, California.
- 16. Plaintiff LUIS FLORES ("Flores") is an individual residing in Santa Cruz County, California.
- 17. Plaintiff STEVEN BERGER ("Berger") is an individual residing in Los Angeles County, California.
- 18. Plaintiff ELIGIO TORRES ("Torres") is an individual residing in Maricopa County, Arizona.
- 19. Plaintiff ROBERT BAKER ("Baker") is an individual residing in Columbia County, Pennsylvania.

II. Defendants

A. Gencor Defendants

- 20. Defendant GENCOR NUTRIENTS, INC. ("Gencor") is a California corporation having its principal place of business in Orange County, California. Prior to August 2008, Gencor was known as Gencor Pacific, Inc. Gencor is the manufacturer of Testofen, a standardized fenugreek extract.
- 21. Defendant GE NUTRIENTS, INC. ("GE Nutrients") is a California corporation having its principal place of business in Orange County, California. A February 20, 2014 article in the Orange County Business Journal reports that GE Nutrients "operates as Gencor."

- 22. Defendant JITH VEERAVALLI ("Veeravalli") is, and at all relevant times has been, the President and Chief Executive Officer of Gencor and GE Nutrients.
- 23. Vecaravalli exercises dominion and control over Gencor and GE Nutrients, and is equally responsible for the wrongful acts alleged herein. Gencor, GE Nutrients, and Vecravalli are collectively referred to herein as the "Gencor Defendants."

B. GNC

- 24. Defendant GENERAL NUTRITION CORPORATION is a Pennsylvania corporation having its principal place of business in Pittsburgh, Pennsylvania. GENERAL NUTRITION CORPORATION manufactures and sells products containing Testofen through GNC branded stores and its website, www.gnc.com.
- 25. Defendant GNC CORPORATION is a Delaware corporation having its principal place of business in Pittsburgh, Pennsylvania. GNC CORPORATION sells products containing Testofen.
- 26. Defendant GENERAL NUTRITION CENTERS, INC. is a Delaware corporation having its principal place of business in Pittsburgh, Pennsylvania. GENERAL NUTRITION CENTERS, INC. sells products containing Testofen.
- 27. Defendant S&G PROPERTIES, LLC is a Pennsylvania limited liability company having its principal place of business in Norristown, Pennsylvania. S&G PROPERTIES, LLC sells products containing Testofen through its website, www.LuckyVitamin.com.
- 28. Defendants GENERAL NUTRITION CORPORATION, GNC CORPORATION, GENERAL NUTRITION CENTERS, INC., and S&G PROPERTIES, LLC (collectively, "GNC") are wholly-owned subsidiaries of GNC Holdings, Inc., a publicly-traded corporation.

C. Manufacturer Defendants

- 29. The defendants identified below manufacture and sell products containing Testofen (collectively, the "Manufacturer Defendants").
- 30. Defendant DIRECT DIGITAL, LLC ("Direct Digital") is a Delaware limited liability company having its principal place(s) of business in Boston, Massachusetts and/or Charlotte, North Carolina. Direct Digital manufactures and sells Nugenix Natural Testosterone Booster, which contains Testofen.
- 31. Defendant TRUDERMA, LLC ("Truderma") is a Nevada limited liability company having its principal place of business in Las Vegas, Nevada. Truderma manufactures and sells Troxyphen and Troxyphen Elite, which contain Testofen.
- 32. Defendant FORCE FACTOR LLC ("Force Factor") is a Delaware limited liability company having its principal place of business in Boston, Massachusetts. Force Factor manufactures and sells several products containing Testofen, including Test X180 Testosterone Booster, Test X180 Alpha, Test X180 Ignite, and Stack Factor 2 With Test X180.
- 33. Defendant NAC MARKETING COMPANY, LLC dba New Vitality ("NAC") is a Delaware limited liability company having its principal place of business in Farmingdale, New York. NAC manufactures and sells Ageless Male containing Testofen.
- 34. Defendant KINGFISHER MEDIA, LLC ("KingFisher") is a Delaware limited liability company having its principal place of business in Midvale, Utah. KingFisher manufactures and sells several products containing Testofen, including High T Testosterone Booster, High T Senior Testosterone Booster, High T Black Hardcore Formulation Testosterone Booster, and High T Black Caffeine Free Hardcore Formulation Testosterone Booster.
- 35. Defendant DREAMBRANDS, INC. ("DreamBrands") is an Arizona corporation having its principal place of business in Phoenix, Arizona. DreamBrands manufactures and sells products containing Testofen, including Mdrive and Mdrive Elite Athlete Formula, which contain Testofen.

- 36. Defendant PHARMAFREAK HOLDINGS INC. ("PharmaFreak") is a Canadian corporation having its principal place of business in Toronto, Ontario. PharmaFreak manufactures and sells Test Freak Hybrid Pro-Testosterone Stimulator, which contains Testofen.
- 37. Defendant NDS NUTRITION PRODUCTS, INC. ("NDS") is a Florida corporation having its principal place of business in Omaha, Nebraska. NDS manufactures and sells PMD N-TEST 600, which contains Testofen, and PMD Flex Stack, which includes PMD N-TEST 600.
- 38. Defendant MEDICAL RESEARCH INSTITUTE, INC. ("MRI") is a California corporation having its principal place of business in the County of Los Angeles, California.

 MRI manufactures and sells NO2 Red Test, which contains Testofen.
- 39. Defendant PREVENTION, LLC is a Delaware limited liability company having its principal place of business in Orange County, California. Naturade, a division of Prevention, LLC, manufactures and sells several products containing Testofen, including Ageless Ultra T Gold, Vitali-T-Aid, and Vitali-T-Aid Energy. Prior to the formation of Prevention, LLC in March 2012, these products were manufactured and sold by Naturade as a division of defendant NNC LLC, a Delaware limited liability company, which maintains its principal place of business at the same address as Prevention, LLC. Prevention, LLC and NNC LLC are individually and collectively referred to herein as "Naturade."
- 40. Defendant PREMIUM NUTRACEUTICALS, LLC ("Premium Nutraceuticals") is a Georgia limited liability company having its principal place of business in Martinez, Georgia. Premium Nutraceuticals manufactures and sells Testoril, which contains Testofen.
- 41. With the exception of Vitali-T-Aid and Vitali-T-Aid Energy, the aforementioned products manufactured by Direct Digital, Truderma, Force Factor, NAC, KingFisher, DreamBrands, PharmaFreak, NDS, MRI, and Naturade (collectively, the "GNC Suppliers") are sold by GNC.

D. Doe Defendants

42. Plaintiffs are ignorant of the true names and capacities of the defendants sued herein under the fictitious names Does 1 through 100. Each of the fictitiously named defendants is responsible in some manner for the acts herein alleged, and proximately caused Plaintiffs' damages. Plaintiffs will seek leave of court to amend this complaint to allege said defendants' true names and capacities as soon as Plaintiffs ascertain them.

E. Civil Conspiracy, Agency, and Alter Ego

- 43. At all times mentioned herein, each defendant was the agent for each other defendant, was acting in the course and scope of such agency, and was engaged in a civil conspiracy to do the things herein alleged.
- 44. At all times mentioned herein, Gencor and GE Nutrients were and are the alter ego of Veeravalli.

COMMON FACTUAL ALLEGATIONS

III. Gencor's Representations Concerning Testofen

- 45. Gencor's website, <u>www.gencorpacific.com</u>, states that its mission is to "support changing human health needs across the lifespan through innovative, clinically proven ingredients," and that "Our herbal ingredients have been clinically studied and shown effective in both animal and human clinical trials."
- 46. One of the herbal ingredients manufactured and sold by Gencor is Testofen, a standardized extract of the herb Trigonella foenum-graecum, commonly known as fenugreek. The name of the product, Testofen, is an amalgamation of the words "testosterone" and "fenugreek." Gencor sells Testofen to manufacturers of nutritional supplements, including the other defendants named herein, for inclusion in their products, which are marketed and sold as clinically-proven "testosterone boosters."
 - 47. On the page devoted to Testofen (Exh. 1), Gencor's website states that:

 Testofen is the branded name for Gencor's fenugreek extract.

 Fenugreek is a well-known, versatile herb that contains over 100 phytochemical constituents, including Furostanol Saponins and Steroidal Saponins. While fenugreek has multiple health

14

15

16

17 18

19

20 21

22

23 24

25

26 27

28

applications, the active constituents included in Testofen have been shown to boost testosterone levels and thereby increase libido, lean muscle mass and immune functions. The group of saponin glycosides that Testofen is standardized to is named Fenuside.

After age 30, most men begin to experience a natural and gradual decline in testosterone levels, which can result in reduced drive and libido and a slow loss of muscle tone and definition. Most of the testosterone found in men is bound to the Sex Hormone Binding Globulin (SHBG) and Albumin. Only 2–3% of the testosterone present in the human body is typically in a free state.

Testofen has been shown to increase free testosterone, up to 98 percent, in an eight-week trial (see below).

48. Under the heading "Clinical research," Gencor's website states:

Human study on free testosterone levels and performance

Study Results: A double-blind, randomized, placebo-controlled human clinical study of 60 subjects was conducted using Testofen as the sole ingredient. The active group demonstrated the following statistically significant results:

Significant increase in free testosterone (p<0.05) compared to placebo group

Citation: Wankhede et. al., 2006 "Effect of Testofen on safety, anabolic activity and factors affecting exercise physiology." To be published.

- 49. Below the citation to "Wankhede et al." (hereafter, the "Testofen Study") is a link for visitors to "Request Complete Study," which generates a pop-up window stating: "To request the complete study document in PDF format please enter your email address below." Such requests are consistently ignored by Gencor.
- 50. Based on the foregoing, the website makes the "Approved health claim" that Testofen "Increases free testosterone levels."
- 51. The website features a video of Gencor's Chief Scientific Advisor, Paul Clayton, Ph.D. (available at http://www.youtube.com/embed/NL 4G13Y1is?autoplay=1), whom Gencor describes as "the UK's leading expert in the fast-developing science of pharmaco-nutrition." In the video, Dr. Clayton states that Testofen:

results in approximately a doubling of free testosterone levels. Now that's important because as we get older, and as we get more stressed, more tired by the constant demands of work and life in general, very often testosterone levels fall, and as they do we

experience a loss of libido, of drive, muscle tone as well, because testosterone is very important in building muscles. By taking Testofen and achieving a doubling of free testosterone levels all of these adverse changes are reversed

IV. Statistical Principles for Clinical Trials

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH") *Harmonised Tripartite Guideline*, *Statistical Principles For Clinical Trials*, *E9* (Feb. 4, 1998) (the "ICH Guideline") sets forth principles for the statistical analysis of human clinical trials that have been adopted by the regulatory bodies of the European Union, Japan, and the United States, including the U.S. Department of Health and Human Services, Food and Drug Administration's ("FDA's") Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research. The ICH Guideline is available on the FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073137.pdf.

A. Exploratory Studies and Confirmatory Trials

53. The ICH Guideline explains the difference between an "exploratory study" and a "confirmatory trial" as follows:

A confirmatory trial is an adequately controlled trial in which the hypotheses are stated in advance and evaluated. As a rule, confirmatory trials are necessary to provide firm evidence of efficacy or safety. In such trials the key hypothesis of interest follows directly from the trial's primary objective, is always pre-defined, and is the hypothesis that is subsequently tested when the trial is complete. [Section 2.1.2 (emphasis added).]

The rationale and design of confirmatory trials nearly always rests on earlier clinical work carried out in a series of exploratory studies. Like all clinical trials, these exploratory studies should have clear and precise objectives. However, in contrast to confirmatory trials, their objectives may not always lead to simple tests of pre-defined hypotheses. . . Such trials cannot be the basis of the formal proof of efficacy, although they may contribute to the total body of relevant evidence.

The protocol should make a clear distinction between the aspects of a trial that will be used for confirmatory proof and

the aspects that will provide data for exploratory analysis. [(Section 2.1.3 (emphasis added).]

B. Primary and Secondary Variables

54. The ICH Guideline explains the difference between a "primary variable" or "endpoint," and a "secondary variable" as follows:

The primary variable ('target' variable, primary endpoint) should be the variable capable of providing the most clinically relevant and convincing evidence directly related to the primary objective of the trial. There should generally be only one primary variable.

To avoid multiplicity concerns arising from post hoc definitions, it is critical to specify in the protocol the precise definition of the primary variable as it will be used in the statistical analysis.

Redefinition of the primary variable after unblinding will almost always be unacceptable, since the biases this introduces are difficult to assess. When the clinical effect defined by the primary objective is to be measured in more than one way, the protocol should identify one of the measurements as the primary variable on the basis of clinical relevance, importance, objectivity, and/or other relevant characteristics, whenever such selection is feasible.

Secondary variables are either supportive measurements related to the primary objective or measurements of effects related to the secondary objectives. [Section 2.22 (emphasis added).]

C. Multiplicity

55. In human clinical trials for efficacy, statistical significance is established by having a probability or "p" value of less than 0.05, usually expressed as "p < 0.05." In layman's terms, this means that there is less than a 5% (one in twenty) probability that the observed difference in the primary variable between the treatment and placebo or other control group is due to chance. The greater the number of variables being analyzed from a single trial, the greater the likelihood of a false positive result, called "Type I error" in statistical parlance, unless corrective statistical techniques are applied. That is, if each statistical test has a 5% chance of producing a false positive, then the overall chances of *some* false positive amongst

multiple tests will be much greater than 5%. This is often denoted as the "family-wise Type I error rate," where "family" refers to the set, or family, of hypotheses being considered.

- 56. To illustrate, imagine you had a roulette wheel with only 20 pockets in which the ball could land, instead of the usual 38. Place a bet on any single number a single primary variable, if you will and the odds that the ball will land in the corresponding pocket, producing a winner, are 1 in 20. Place bets on *two* numbers two primary variables, if you will and the odds that the ball will land in *one* of the corresponding pockets, producing a winner, are 1 in 10, not 1 in 20.
- 57. This problem is known generally as "multiplicity." *See* ICH Guideline, Section 2.2.5 ("It may sometimes be desirable to use more than one primary variable The effect on the Type I error should be explained because of the potential for multiplicity problems (*see* Section 5.6); the method of controlling type I error should be given in the protocol."). As the ICH Guideline explains:

When multiplicity is present, the usual frequentist approach to the analysis of clinical trial data may necessitate an adjustment to the type I error. Multiplicity may arise, for example, from multiple primary variables (see Section 2.2.2) Methods to avoid or reduce multiplicity are sometimes preferable when available, such as the identification of the key primary variable (multiple variables) . . . In confirmatory analyses, any aspects of multiplicity that remain after steps of this kind have been taken should be identified in the protocol; adjustment should always be considered and the details of any adjustment procedure or an explanation of why adjustment is not thought to be necessary should be set out in the analysis plan. [Section 5.6.]

58. Testofen was developed by Indus Biotech Pvt. Ltd., which is located in India. As one Indian medical journal recently explained:

In most of the clinical trials published in Indian medical journals multiple end points are measured and hence multiple statistical tests are used to measure the difference between groups. This may lead to increase in false positivity or Type 1 error. The P value is based on principal of probability, if with one statistical test the chance of having a significant result is 5%, then after 20 statistical tests it may be more than 40%. This is called inflation of type 1 error. More the number of statistical tests more inflation of Type 1 error. Inflation of type 1 error can be prevented dividing the

endpoints at the design phase itself into primary and secondary endpoints. Most important endpoint should be considered as primary endpoint and other endpoints should be considered as secondary endpoints. If the primary endpoint cannot be restricted to one then multiple endpoints should be adjusted with the help of various adjustment methods like Bonferroni method, least significant difference test, composite endpoint method etc. In a study . . . done for clinical trials published in Indian medical journals it was found that about one third of the clinical trials published in four Indian journals were false positive and statistical methods used to adjust this error was not mentioned in even a single trial.

J. Charan, D. Saxena, *Suggested Statistical Reporting Guidelines for Clinical Trials Data*, Indian J Psychol Med 2012 Jan-Mar; 34(1): 25-29 (available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3361838/).

D. The Bonferroni Correction

- 59. The simplest and most commonly used method of making such adjustments is known as the "Bonferroni correction." See http://en.wikipedia.org/wiki/Bonferroni_correction. The correction is based on the observation that, if k tests are being evaluated separately, the family-wise Type I error rate is at most k times 0.05 if each test uses a standard 0.05 significance level. To obtain an overall significance level for the whole family of tests at a significance level of 0.05, the Bonferroni correction states that each individual test should be carried out using a significance level of 0.05/k. See Wright, Adjusted p-values for simultaneous inference, Biometrics, 1992, 1005-1013.
- . Accordingly, if there are two primary variables or endpoints, applying the Bonferroni correction, the threshold for statistical significance for each of the two variables is 0.025 (0.05/2). If there are three primary variables, the threshold for statistical significance for each of the three variables is 0.016 (0.05/3), etc.

V. The Testofen Study

A. The Protocol

61. The protocol for the Testofen Study, entitled "EFFECT OF IND 6 ON MUSCULAR STRENGTH, ENDURANCE AND BODY COMPOSITION," Project Code:

IBHM05/2006, Test Formulation: IND6, dated May 24, 2006, sponsored by INDUS BIOTECH PVT LTD., Principal Investigator: Dr. Sachin Wankhede, Pune (the "Protocol"), identifies it as an "exploratory study," stating that "This trial, being an exploratory study, no statistical method is applied to determine the sample size" (Page 18, Section 9.) "Such trials cannot be the basis of the formal proof of efficacy." ICH Guideline, Section 2.1.3.

- 62. The Protocol defines the "PRIMARY OBJECTIVES" of the Study as: (a) "To determine the effects of IND6 [Testofen] on muscle strength and endurance during eight weeks of resistance exercise;" and (b) "To evaluate safety of the test supplement." (Page 7, Section 4.1.)
- 63. The Protocol states that "Primary efficacy will be assessed on the basis of the following parameters" of "Muscular Strength and Endurance": (a) "Change in 1-RM Bench Press;" (b) "Change in 1-RM Leg Extension;" (c) "Change in Bench Press repetitions at 80% of 1-RM at baseline;" and (d) "Change in Leg Extension repetitions at 80% of 1-RM at baseline." (Page 14, Section 8.1.)
- 64. The Protocol defines the "SECONDARY OBJECTIVES" of the Study as: (a) "To determine the effects of the ingestion of IND6 on muscle size during eight weeks of resistance exercise." (b) "To determine the effects of the ingestion of IND6 on body composition during eight weeks of resistance exercise." and (c) "To assess effect of IND6 on serum testosterone (total and free) and prolactin levels." (Page 7, Section 4.2.)
- 65. Under the heading "CLINICAL EFFICACY ASSESSMENTS," the Protocol states that "Secondary efficacy will be assessed on the basis of the following parameters: (a) Muscle size (i) Change in thigh: maximal girth, inferior to the gluteal fold, (ii) Change in flexed arm: maximal girth at mid upper arm, elbow flexed and muscle contracted, (iii) Change in shoulders: across the maximal protrusion of the deltoids, (iv) Change in chest: mid-tidal volume;" and (b) "Body Composition (i) Change in Fat-Free Mass, (ii) Change in Percent Body Fat, (iii) Change in Fat Mass, and (iv) Change in Body Weight." (Page 14, Section 8.1.)

66. Under the heading "LABORATORY EFFICACY ASSESSMENTS," the Protocol states that "Secondary efficacy will be assessed by measuring changes from baseline in serum testosterone (total and free) and prolactin levels after 8 weeks." (Page 15, Section 8.3.)

67. Accordingly, as defined by the Protocol, determining the effect of Testofen on free testosterone levels was not the primary objective of the Testofen Study, but one of three secondary objectives, and free testosterone levels was not one of four primary variables noted, but one of at least three (and perhaps as many as ten) secondary variables.

VI. The Testofen Study

- 68. Gencor has made publicly available three versions of the Testofen Study purporting to support its claim that Testofen has been clinically proven to increase free testosterone levels: (1) a version entitled "Testofen Human Clinical Trial," Copyright 2006 by Gencor Pacific, Inc. (the "2006 Report") (Exh. 2); (2) a version entitled "Human Clinical Study for Free Testosterone & Muscle Mass Boosting," Copyright 2008 by Gencor Nutrients, Inc. (the "2008 Report") (Exh. 3); and (3) a duplicate of the 2008 Report, Copyright 2013 by GE Nutrients, Inc. (Exh. 4).
- 69. Gencor has also provided Plaintiffs' counsel with: (a) an undated and unpublished manuscript concerning the Testofen Study entitled "Beneficial effects of fenugreek glycosides supplementation in weight resistance trained male subjects: A prospective, double-blind, randomized, placebo controlled study" (the "Manuscript"); and (b) an Excel spreadsheet containing the individual data points for the 60 subjects enrolled in the Testofen Study (the "Study Data").

A. The 2006 Report

70. The 2006 Report identifies the Testofen Study as an exploratory study "designed to explore the efficacy and safety of TESTOFEN in healthy male volunteers," and

states that "Primary objectives of the study were to determine the effects of TESTOFEN on free testosterone and body composition during eight weeks of resistance exercise and to evaluate safety of TESTOFEN." (Page 2.)

- 71. As set forth above, effect on body composition and free testosterone levels were secondary, not primary objectives of the Testofen Study, and secondary, not primary variables. The primary objective of the Testofen Study, to determine the effects of Testofen on muscle strength and endurance, and the primary efficacy measures (*see* Paragraph 63, above) are not mentioned in the 2006 Report.
- 72. The 2006 Report shows pre-treatment and post-treatment free testosterone levels for the Testofen group, but makes no claim of statistical significance.
- 73. In addition to body composition measures, the 2006 Report presents blood urea nitrogen ("BUN") levels as a third variable.
- 74. Under the heading "Safety," the 2006 Report lists 20 "biochemical parameters [that] were analyzed for the active and placebo groups," including "Creatinine" and "Lymphocytes," and states that "All of the parameters were normal for all participants."

B. The 2008 Report

- 75. The 2008 Report identifies the "PRIMARY CLINICAL END POINTS" of the Testofen Study as "To determine the effect of TESTOFEN on Safety, Anabolic Activity, Blood Testosterone, Immune Function," and the "SECONDARY CLINICAL END POINTS" as "To determine the effects of TESTOFEN on body composition, Creatinine, Prolactin, and Muscle mass variation." [Page 3.]
 - 76. The 2008 Report states that:

Primary efficacy was assessed on the basis of following parameters:

- I. Anabolic Activity by Nitrogen Absorption measured by BUN
- II. Blood testosterone both Total and Free
- III. Total Lymphocyte count and check immunity. [Page 8.]

12

24

77. The 2008 Report states that:

Secondary efficacy will be assessed on the basis of following parameters:

- 1. Exercise Physiology Biomarkers
 - Serum Creatinine
 - Serum Prolactin
- 2. Body Composition
 - Change in Fat-Free Mass
 - Change in Percent Body Fat
 - Change in Fat Mass
 - Change in Body Weight
- 3. Muscle size
 - Change in thigh: maximal girth, inferior to the gluteal fold.
 - Change in flexed arm: maximal girth at mid upper arm, elbow flexed and muscle contracted.
 - Change in shoulders: across the maximal protrusion of the deltoids.
 - Change in chest: mid-tidal volume. [Page 8.]
- 78. As set forth above, the effect on free testosterone levels was a secondary, not primary objective of the Testofen Study, and free testosterone levels was one of numerous secondary variables. The primary objective of the Testofen Study, to determine the effects of Testofen on muscle strength and endurance, and the primary efficacy measures (*see* Paragraph 63, above) are not mentioned in the 2008 Report.
- 79. The 2008 Report presents the results for the three purported "primary efficacy parameters," BUN, free testosterone, and lymphocytes, followed by the results for the purported "secondary efficacy parameters" creatinine, prolactin, body composition (three submeasures), and muscle size (four sub-measures). No results are presented for total testosterone, despite its inclusion in the list of "primary efficacy parameters."
 - 80. The 2008 Report presents the following results for free testosterone (pg/ml):

PARAMETERS	TESTOFEN	PLACEBO	
Pre Treatment	17.76	21.30	
Post Treatment	35.29	31.70	
P value	0.0001	0.014	
Percentage	96	48	P Value < 0.05
change			

- 84. The 2008 Report states that "Primary efficacy was assessed on the basis of the following parameters: I. Anabolic Activity by Nitrogen Absorption measured by BUN" (Page 8), and that "TESTOFEN group has demonstrated significant anabolic activity as evidenced by BUN reduction (p < 0.05) compared to placebo." (Page 11, Conclusion 1.) BUN is not identified as either a primary or secondary efficacy measure in the Protocol, but as the **thirteenth of fourteen "routine laboratory test(s)."** Thus, the 2008 Report represents that a "routine laboratory test" performed for safety was instead the first of three primary efficacy measures.
- 85. The 2008 Report represents that the other two primary efficacy measures are "II. Blood Testosterone both Total and Free" (discussed above), and "III. Total Lymphocyte count and check immunity." (Page 8.) The 2008 Report states that "Testofen has a significant increase in Lymphocytes with respect to Placebo (p < 0.03)" (Page 9), from which the author(s) concludes that "TESTOFEN group has not only compensated the loss of Immunity significantly compared to Placebo (p < 0.003), but has also increased immunity." (Page 11, Conclusion 3.) There is no mention of lymphocyte count in the Protocol, as either a primary or secondary variable of interest, or even as one of the fourteen enumerated "routine laboratory tests." Lymphocytes are but one of the five types of white blood cells counted in the differential white blood cell (WBC) "routine laboratory test" called for by the Protocol. *See* http://www.nlm.nih.gov/medlineplus/ency/article/003657.htm.
- 86. The 2008 Report identifies as a "SECONDARY CLINICAL END POINT" "To determine the effects of TESTOFEN on . . . Creatinine, . . ." (Page 3); states that "Secondary efficacy will be assessed on the basis of 1. Exercise Physiology Biomarkers Serum Creatinine" (Page 8); and that "TESTOFEN group has shown significant reduction in Serum Creatinine levels (p < 0.02) compared to placebo signifying Creatinine uptake and recycle in muscle cell." (Page 11, Conclusion 4.) Creatinine is not identified as either a primary or

secondary efficacy measure in the Protocol, but as the **last of fourteen "routine laboratory test(s)."**

- 87. The 2008 Report concludes that "TESTOFEN group has shown significant increase in Prolactin compared to Placebo (p < 0.04)." (Page 11, Conclusion 5.). Prolactin is identified in the Protocol as a secondary outcome measure.
- Thus, none of the first five claims of statistical significance made in the 2008 Report (BUN, free testosterone, lymphocyte count, creatinine, and prolactin) are identified as primary outcome measures in the Protocol; two (BUN and creatinine) are not identified as primary or secondary outcome measures, but as the thirteenth and fourteenth of fourteen "routine laboratory tests" which the Protocol itself expressly distinguishes from "laboratory efficacy assessments;" and one (lymphocyte count) is not mentioned in the Protocol at all.

C. The Manuscript

- 89. The Manuscript identifies the aim of the Testofen Study as determining the "efficacy and safety [of Testofen] on physiological parameters related to muscle anabolism, androgenic hormones and body composition" (Page 1.)
- 90. The Manuscript identifies the "efficacy outcome measures of study" as "markers of anabolic activity (serum creatinine and blood urea nitrogen (BUN) to measure nitrogen metabolism), body composition (skinfold thickness and % body fat), male androgenic hormone profile (total and free testosterone levels in blood), muscular strength and endurance (bench press and leg press)" (Page 6, Section 2.4.) **The Manuscript makes no distinctions whatsoever between primary or secondary objectives of the Testofen Study, or between primary and secondary efficacy measures.** Indeed, neither the word "primary" nor "secondary" appears in the Manuscript. The Protocol classifies creatinine and BUN as "routine laboratory tests," not efficacy measures.

- 91. As to the primary objective identified in the Protocol, effect on muscle strength and endurance, the Manuscript concludes that "no statistically significant difference [was] found between 1 RM-bench press, and or muscle endurance (Maximum repetitions) in leg press and bench press exercises." (Page 7, Section 3.2.)
- 92. The Manuscript also concludes that "The change in total testosterone from baseline was . . . not significant between the treatment groups." (Page 7, Section 3.3.)
- 93. As to the effect of Testofen on free testosterone levels, the Manuscript states that "The change in free testosterone from baseline (Fenu-FG: 17.53 ± 8.55 ; Placebo: 10.39 ± 14.71) was found significant between the groups at P < 0.05." (Page 7.)
- 94. The following table summarizes Gencor's shifting identification of the primary variables, secondary variables, and routine laboratory (*i.e.*, safety) tests, involved in the Testofen Study:

Document	Primary Variable(s)	Secondary Variables	Safety
Protocol	Muscle Strength and Endurance	Muscle Size (4 sub-measures) Body Composition (4 sub-measures) Total testosterone Free testosterone Prolactin	WBC BUN Creatinine
2006 Report	Free testosterone Body Composition (2 sub-measures)	BUN	Creatinine Lymphocytes
2008 Report	BUN Total testosterone Free testosterone Lymphocytes	Creatinine Prolactin Body Composition (3 sub-measures) Muscle Size (4 sub-measures)	
Manuscript	Creatinine BUN Body Composition (2 sub-measures) Total testosterone Free testosterone Muscle Strength and Endurance		

95. Gencor's deliberate manipulation of the identification of primary and secondary variables after unblinding of the data constitutes scientific fraud of the highest order, and is compelling evidence of the Gencor Defendants' intent to defraud Plaintiffs and the Class by falsely representing that Testofen has been clinically proven to increase free testosterone levels.

D. The Results Are Not Statistically Significant

- 96. Plaintiffs have retained Professor Nicholas P. Jewell, a Professor of Biostatistics at the University of California, Berkeley, to determine whether Testofen has been clinically proven to increase free testosterone levels. Professor Jewell is the author of the textbook "Statistics for Epidemiology" (Chapman and Hall, New York 2003), as well as approximately 160 peer-reviewed articles in the field of biostatistics, and recently served as Chair of the Section on Statistics in Epidemiology of the American Statistical Association (2009-2012).
- 97. Professor Jewell's expert report is attached as Exhibit 5. Professor Jewell has determined that Testofen has *not* been clinically proven to increase free testosterone levels, and that Defendants' claims to the contrary are *false*. In making this determination, Professor Jewell reviewed the Protocol, the 2006 Report, the 2008 Report, the Manuscript, and the Study Data. (Exh. $5 \, \P \, 7$.)
 - 98. Professor Jewell summarized his conclusions as follows:

According to the Protocol, determining the effect of Testofen on free testosterone levels was not the primary objective of the Study, and change in free testosterone levels was not included as one of at least twelve primary outcome variables, but rather one of at least three secondary outcome variables. Under universally accepted principles of statistical analysis, the threshold for statistical significance must be adjusted upward to reflect this multiplicity of comparisons. After making required adjustments, the results are not statistically significant with regard to free testosterone as claimed, regardless of the particular method of adjustment employed. Accordingly, the Claim is false. (Exh. 5 ¶ 8, emphasis added.)

99. In particular, Professor Jewell explains that:

A set forth above, in addition to the measurement and comparison of total and free testosterone, the Study includes primary efficacy measures of "muscular strength and endurance" (four submeasures), and secondary efficacy measures of "muscle size" (four sub-measures), "body composition" (four sub-measures), and prolactin. Assuming, arguendo, that each of these sub-measures were perfectly correlated with one another, and that total testosterone, free testosterone, and prolactin levels were perfectly correlated (which is clearly not the case, as change in total testosterone levels is not significant even absent correction), the Bonferroni corrected significance level for each individual test would be 0.05/4 = 0.0125. Even with these heroic assumptions, the nominal p-value of 0.030 demonstrated here, associated with comparing free testosterone changes across the Testofen and Placebo groups, is not statistically significant.

While there are other, more sophisticated (and less conservative) methods to adjust for the problem of multiplicity, which may take into account the degree of correlation among the variables of interest, *none produces a statistically significant result here for comparison of free testosterone changes across the two treatment groups*. (Exh. 5 ¶¶ 48-49, emphasis added.)

100. As Professor Jewell explains in the appended Supplemental Statement:

As stated in my Report, my "opinions, contained herein, are all stated to a reasonable degree of scientific certainty," although I "reserve[d] the right to supplement this preliminary report if new, or significantly modified, quantitative information is provided at any point." (Report, para. 5.) It has been over a year since Gencor received my Report, but no "new or significantly modified quantitative information" has been provided. As my analysis was conducted on what Gencor represented was the full data set (the "Data"), I have no reason to believe that any such new or modified quantitative information exists. My Report is and has been final, absent such new or modified information. (Exh. 5, Supplemental Statement ¶ 2.)

101. In his Supplemental Statement, Professor Jewell reiterates his conclusion that "Gencor's claim that Testofen produced a statistically significant increase in free testosterone levels in a clinical trial is false." (Exh. 5, Supplemental Statement ¶ 5, emphasis added.)

VII. Other Negative Studies

102. In addition to the Testofen Study, at least three other studies sponsored by Indus Biotech have found that fenugreek extract has *no effect* on free testosterone levels.

103. A human clinical trial conducted in Australia comparing Testofen to placebo found that Testofen "did not affect testosterone" levels. E. Steels, *et al.*, Physiological Aspects of Male Libido Enhanced by Standardized *Trigonella foenum-graecum* Extract and Mineral Formulation, *Phytotherapy Res.* 25: 1294-1300 (2011) (Exh. 6).

104. Another study, sponsored by Indus Biotech, concluded that fenugreek extract has *no effect* on free testosterone levels:

Despite no substantiated claims in human research models, fenugreek has been marketed in dietary products as having anabolic potential for resistance trained athletes. . . . The purpose of this study was to investigate the potential anabolic effects of fenugreek extract supplementation in conjunction with a controlled resistance training program. . . . No significant effects for groups or interactions were observed for the anabolic hormone[] free testosterone . . . (p<0.05). . . . [S]upplementation of fenugreek extract does not appear to affect hormonal status in resistance trained males and shows no anabolic potential as has been purported. This study was supported by INDUS BIOTECH.

- B. Bushey, *et al.*, Fenugreek Extract Supplementation Has No Effect on the Hormonal Profile of Resistance-Trained Males, *Int. J. Exerc. Sci.* 2(1): S13, 2009 (Exh. 7).
- 105. Another study, also sponsored by Indus Biotech, also concluded that fenugreek extract has no effect on free testosterone levels. *See* C. Poole, *et al.*, Effects of TESTOSURGE supplementation on strength, body composition and hormonal profiles during an 8-week resistance training program, *J. Int. Soc. Sports Nutrition* 2009, 6(Suppl. I): P12 ("No significant changes were detected among groups for . . . free testosterone") (Exh. 8).
- 106. Yet another study, also sponsored by Indus Biotech, found a significant difference in free testosterone levels between the group taking fenugreek extract and the placebo group, but the difference was *in favor of the placebo group*, whose free testosterone levels rose by an average of 10 ng/ml over the course of the study, compared to the fenugreek group, whose free testosterone levels *declined* by an average of 4 ng/ml. C. Poole, *et al.*, The effects of a commercially available botanical supplement on strength, body composition, power output, and hormonal profiles in resistance-trained males, *J. Int. Soc. Sports Nutrition* 2010,

7:34 (Table 5) (Exh. 9). Rather than finding a *negative* effect on free testosterone levels, the study concluded that fenugreek extract has *no* effect:

Fenugreek supplementation is surrounded by assertions of having anabolic potential, even though there is no scientific data supporting this notion. In the present study we examined serum hormone variables that included free testosterone . . . Although a between group difference was noted for free testosterone at T2 and T3, it has limited relevance due to the fact that it did not significantly change over time. . . . [D]aily consumption of the 500 mg commercially available [fenugreek] supplement in conjunction with a resistance training program has no anabolic effect on the hormonal status of resistance trained males. [Page 8.]

VIII. False Representations Concerning "Testosterone Boosters"

107. Despite the fact that Testofen has *not* been shown to increase free testosterone levels, and the existence of *four published studies* showing that it has no such effect, more than 20 products containing Testofen are marketed and sold as clinically proven "testosterone boosters." False representations concerning each of these products are set forth below.

A. Nugenix

1. <u>Label and Packaging</u>

- 108. The label affixed to the product Nugenix Natural Testosterone Booster ("Nugenix") (Exh. 10) states that "Nugenix is an all natural Testosterone booster that contains clinically studied ingredients that are proven to boost free testosterone levels."
 - 109. The box in which Nugenix is packaged (Exh. 11) states:

RECLAIM YOUR STRENGTH, STAMINA, AND SEXUAL PERFORMANCE . . .

As you age testosterone levels can decrease, resulting in lowered muscle mass and decreased libido. All natural Nugenix helps your body restore testosterone levels Clinical studies have shown Testofen to increase free testosterone levels by over 98%.

110. The box contains a bar graph entitled "TESTOSTERONE DECLINE," showing a steady decline in "TESTOSTERONE LEVELS" from age 20 to age 70. Beneath this bar graph, the box states: "After age 30, most men begin to experience a gradual decline in testosterone. Nugenix helps fight this decline."

2. Website

111. The website www.nugenix.com is owned by defendant Direct Digital. The website (Exh. 12) states:

BOOST YOUR FREE TESTOSTERONE NOW

Our developers formulated NUGENIX to provide high levels of TESTOFEN...the key to boosting free testosterone.

Nugenix Testosterone Booster is a safe and specially formulated dietary supplement that helps your body increase its free testosterone.

BOOST YOUR TESTOSTERONE NOW

Our Cambridge developers formulated Nugenix to provide some of the highest levels of Testofen ... the Key to Natural Testosterone production.

STUDIES AND TESTS SHOW THE MAIN INGREDIENT IN NUGENIX IS EFFECTIVE

Testofen Studies in Irvine, California and Queensland, Australia produced the following results.

• Significant increase in natural testosterone compared to placebo test group.

And remember, our Cambridge developers created the blend for Nugenix with the clinically proven dosage of Testofen for great results

B. Troxyphen

1. <u>Label and Packaging</u>

112. The label and packaging for Troxyphen (Exh. 13) describe it as "A unique [weight loss] supplement designed to specifically address the underlying cause of male weight gain: LOW TESTOSTERONE," and state that it contains "INGREDIENTS SHOWN TO HELP: RAISE TESTOSTERONE." The remainder of the packaging is devoted to drawing a link between "Low Testosterone and Excess Fat," and states that Troxyphen is "designed to specifically address the underlying cause of male weight gain. By naturally and significantly increasing your base line testosterone levels"

113. The label and packaging for Troxyphen Elite (Exh. 14) state that it is "A Powerful Free Testosterone Booster" containing "INGREDIENTS SHOWN TO HELP: RAISE FREE TEST LEVELS," and that "TROXYPHEN ELITE helps to increase your free testosterone levels"

2. Radio

114. Troxyphen is the subject of a national radio advertising campaign, on both broadcast and satellite radio, including stations such as CNN. The radio commercial, which has aired thousands of times, states that "Troxyphen is GNC's best-selling, 100% natural and most powerful testosterone booster. Troxyphen raises testosterone" The commercial states that "Troxyphen is available nationwide at GNC stores," and also directs listeners to the website, "stoplowt.com" or "raisemytest.com."

3. Websites

115. The websites <u>stoplowt.com</u> and <u>raisemytest.com</u> (which is redirected to the website <u>www.troxyphen2.com</u>) (Exh. 15) state:

TROXYPHEN
ADVANCED TESTOGENIC
TESTOSTERONE BOOSTING THERMOGENIC

TROXYPHEN IS AN ADVANCED SUPPLEMENT DESIGNED TO BOOST FREE TESTOSTERONE LEVELS

TESTOSTERONE INCREASED 98%

By naturally and significantly increasing your base line testosterone levels . . .

TROXYPHEN IS SAFE & CLINICALLY RESEARCHED TROXYPHEN was developed around the clinically researched and patented Testofen.

TESTOSTERONE BOOSTING BLEND
The patented test boosting blend was shown in clinical studies to:
RAISE TESTOSTERONE LEVELS 98.81% IN 8 WEEKS

TESTOFEN

Testofen is a natural solution for promoting Healthy Free Testosterone levels . . .

THE CHOICE IS YOURS! DO NOTHING AND GET Lowering Testosterone Levels

PICK TROXYPHEN AND ENJOY Increased Testosterone Levels by 98%

C. Ageless Male

1. Label and Packaging

116. The label and packaging for Ageless Male (Exh. 16) state that it has been "Clinically Shown to Increase Free Testosterone Levels," and contains "Ageless Male Proprietary Blend Testofen," which "has been shown in a human clinical study to help support healthy free testosterone levels."

2. Television

- 117. A 60-second television commercial for Ageless Male, available at http://www.ispot.tv/ad/7nXX/ageless-male-giveaway, has aired nationally 4,695 times, including on April 1, 2014 at 10:30 a.m. PST on SYFY. The commercial states that "Ageless Male has ingredients clinically shown to increase free testosterone levels," and directs viewers to the website AgelessMaleFree.com.
- 118. A 120-second television commercial for Ageless Male, available at http://www.ispot.tv/ad/77kP/ageless-male-over-40, has aired nationally 2,164 times, including on November 29, 2013 at 11:57 a.m. PST on IFC. The commercial states that Ageless Male is "clinically shown to help increase testosterone levels," and directs viewers to the website TryAgelessMale.com
- http://www.ispot.tv/ad/7nXh/ageless-male-featuring-walt-frazier, has aired nationally 324 times, including on December 23, 2013 at 2:42 a.m. PST on Smithsonian. The commercial states that Ageless Male's "active ingredient is clinically shown to boost free testosterone," and features Darren Clair, M.D., an Age Management Specialist, who states that "[t]he great thing

about Ageless Male is it increases your *free* testosterone, and that's what you want." The commercial directs viewers to the website MyFreeAgeless.com.

120. A 60-second television commercial for Ageless Male, available at http://www.ispot.tv/ad/7OSr/ageless-male-signs, has aired nationally 21 times, including on July 29, 2013 at 2:28 a.m. PST on Discovery. The commercial states that "Ageless Male is made with natural ingredients clinically shown to help boost free testosterone levels," and directs viewers to the website AgelessMaleFree.com.

3. Websites

- 121. The website www.newvitality.com is owned by defendant NAC. The website (Exh. 17) states that Ageless Male is "Our Best Selling Formula to Boost Healthy Free Testosterone Levels, and describes the product as "The game-changing free testosterone booster for men!" Under the heading "Ageless Male Benefits," the website states "Boost Healthy Free Testosterone Levels."
 - 122. Under the heading "About Ageless Male," the website states that:

Testosterone is Vital for the Health of Any Man

Perhaps more than any other hormone, testosterone defines who a man is and supports his wellbeing. That's why it's so important for men to maintain healthy testosterone levels. The key ingredients in Ageless Male have been clinically-shown to help do just that by supporting free testosterone levels.

Boost Free Testosterone Naturally... and More!

Ageless Male contains an ingredient derived from the Fenugreek herb called Testofen – shown in a human clinical study to significantly help boost free testosterone (the most important form of testosterone which is available for immediate use by the body) in men.

123. Under the heading "FAQs," the website states:

Q. Why should I consider Ageless Male?

A. Shown to be safe with no major side effects, Ageless Male contains a key ingredient shown in published research to help significantly boost free testosterone in men.1

Q. What can I expect Ageless Male to do for me?

	1
	2
	3
	4
	5
	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0
2	1
2	2
2	3
2	4
2	5
2	6
2	7

A. You can expect Ageless Male to help boost your free testosterone levels with correct use.

Q. What is the key ingredient in Ageless Male?

A. It's a natural component professionally derived from the fenugreek herb. A double-blind, randomized, placebo-controlled human clinical study on this ingredient has shown it can significantly help boost free testosterone in men.1

Footnote 1 to the FAQs cites the "published research" and "clinical study" as "Effect of TESTOFEN on safety, anabolic activity and factors affecting Exercise Physiology. Wankhede et. al."

- 124. The website www.ageless-male.com is owned by defendant NAC. Visitors to TryAgelessMale.com and AgelessMaleFree.com are redirected to www.ageless-male.com, and visitors to MyFreeAgeless.com are presented with the same content.
- 125. The website (Exh. 18) bills the product as "Ageless Male NATURAL FREE TESTOSTERONE BOOSTER," and states that "Ageless Male has clinically-tested ingredients shown to: Boost healthy free testosterone levels." The website states:

An Exciting Breakthrough

The makers of Ageless Male know the importance of having the right testosterone support as you age. That's why they've combined some of the best, clinically-researched ingredients in one distinct formula to help men significantly increase free testosterone levels.

How Does it Work?

Testosterone is what ultimately makes a man "a man." But did you know free testosterone (the kind available for immediate use in the body) may be the most important type? Ageless Male is made with an ingredient derived from the Fenugreek herb called Testofen—shown in a human clinical study to significantly help boost free testosterone levels.1

126. Under the heading "Frequently Asked Questions," the website contains the same representations as the "FAQs" section of the www.newvitality.com website quoted above.

2

5

6

7

9

10

11

12

13 14

15

16

17

18 19

20

21 22

23

24 25

26

27

28

D. **Test X180**

Label and Packaging

The label and packaging for Test X180 Testosterone Booster ("Test X180") 127. (Exh. 19) contain the following "Product Information":

> How do you safely increase testosterone levels? Well-researched ingredients are the answer, which is why the experts at Force Factor formulated Test X180 with premium, clinically supported compounds like Testofen. There's no reason to take a chance on unsafe, sketchy supplements. The ingredients in our proprietary blend are substantiated with rigorous research and hard, scientific facts – the same smart science behind the entire line of Force Factor products.

128 Under the heading "Test X180 Science," the label and packaging state that:

The experts at Force Factor carefully formulated Test X180 to provide the boost that every man needs. By naturally raising your levels of free testosterone

Each serving of Test X180 contains clinically researched levels of Testofen . . . Testofen is the well-known, effective compound your body needs to combat natural testosterone decline.

There's no need to take a chance on your health with untested, risky ingredients. Look and feel confident while you perform at your peak with the trusted ingredients in Test X180.

129. The label and packaging for Test X180 Alpha (Exh. 20) call the product "THE PREFERRED TESTOSTERONE BOOSTER OF ELITE MEN;" state that "the natural ingredient Testofen is clinically demonstrated to raise your body's free testosterone levels;" and state that "The Force Factor team perfected the Test X180 Alpha formula with one of the only natural ingredients clinically demonstrated to increase free testosterone levels: Testofen." The label and packaging for Test X180 Ignite (Exh. 21) state that the product "was developed to be the ultimate all-in-one free testosterone booster, using safe, trusted ingredients backed by real science. Test X180 Ignite is fueled by Testofen "

2

4

5

6

7

9

10

12

1.3

14

15 16

17

18

19

20

2.2

23

24

25

26

27

28

2. Website

130. The website www.forcefactor.com is owned by defendant Force Factor. The website (Exh. 22) contains the same representations regarding Test X180, Test X180 Alpha, and Test X180 Ignite quoted above, and states that:

You're probably asking: "How do I safely increase my testosterone levels?" Well-researched natural testosterone boosters are the answer. That's how the experts at Force Factor formulated Test X180 – with premium, clinically supported compounds like Testofen that will pump up your testosterone to superhero levels as part of your workout routine.

Test X180 is backed by smart science, not fly-by-night sketchy "science." There's no reason to risk your health and your life with disreputable natural solutions. It's just not worth it.

NATURAL TESTOSTERONE BOOSTER CLINICALLY RESEARCHED INGREDIENTS

HOW TEST X180 WORKS

When taken along with regular exercise, Test X180 works with your body to naturally raise your levels of free testosterone. It doesn't contain any mysterious substances – only premium, rigorously researched, natural ingredients.

STEP ONE

Test X180 permeates the bloodstream

STEP TWO

Testofen goes to work raising your levels of free testosterone.

SERIOUSLY POWERFUL INGREDIENTS

The ingredients in our proprietary blend are substantiated with rigorous research and hard, scientific facts.

TESTOFEN

This clinically researched natural fenugreek seed extract has been shown to help men add hard, sculpted muscle to their bodies by increasing their levels of free testosterone safely and effectively.

E. High T

1. <u>Label and Packaging</u>

131. The label and packaging for High T Testosterone Booster ("High T") (Exh. 23), High T Senior Testosterone Booster ("High T Senior") (Exh. 24), and High T Black Hardcore Formulation Testosterone Booster ("High T Black") (Exh. 25) contain a graph entitled "Male

Testosterone Production With Age," showing a steady decline in "Testosterone Production Capacity %" from age 20 to age 90, and state that "High T has been clinically proven to boost free Testosterone levels" The label and packaging for High T Black Caffeine Free Hardcore Formulation Testosterone Booster ("High T Caffeine Free") (Exh. 26) contains the same graph in another format, and states that "High T has been scientifically formulated to help Testosterone levels"

2. Websites

- 132. The website www.hightproducts.com is owned by defendant KingFisher. The website (Exh. 27) states that High T "boosts testosterone naturally" by increasing "Testosterone levels," and that Testofen "improves testosterone levels" and "helps promote healthy testosterone levels." The website states that High T Senior "is scientifically formulated to benefit a man's health by improving Testosterone levels," and states that the product will "BOOST YOUR TESTOSTERONE LEVELS TODAY By increasing your testosterone levels" The website states that "High T Black has been clinically proven to boost free testosterone levels."
- 133. Under the heading "Science Report" (Exh. 28), the website states that "Key ingredients in High T have been clinically proven to boost free testosterone levels," and that "High T Black has been clinically proven to boost free testosterone levels."

F. Mdrive

1. Label and packaging

134. The label and packaging for Mdrive (Exh. 29) state:

M drive naturally increase testosterone

*Contains a clinically proven ingredient which promotes free testosterone

M-Drive contains Testofen – a Fenugreek Seed Extract clinically proven to promote healthy free testosterone levels

1		Ingredients in M-Drive have been shown to increase testosterone levels
2		*A clinical study of Testofen revealed that it promoted healthy free testosterone levels in the active group of subjects by 98%.
4	135.	A package insert (Exh. 30) states:
5 6		You are, no doubt, aware that very few male performance products actually work as advertised. Mdrive is different. It is backed by legitimate science and formulated with a clinically proven ingredient.
7 8		Our star ingredient is a very specific Fenugreek Seed Extract called Testofen A clinical study of Testofen revealed that it promoted healthy free testosterone levels.
9	136.	The label and packaging for Mdrive Elite Athlete Formula ("Mdrive Elite")
10	(Exh. 31) sta	ate that the product is an "Energizing Testosterone Booster" containing "Clinically
12	Tested Ingre	edients," "Promotes healthy free testosterone levels within the normal range," and
13	"naturally in	creases healthy free testosterone levels." Under the heading, "clinically tested
14	ingredients.	At the clinical levels," the label and packaging state:
15 16		Increase Testosterone Testofen's clinical results confirmed a boost in free testosterone levels in men
17	137.	A package insert (Exh. 32) states:
18 19		Boost Free Testosterone Mdrive Elite contains Fenugreek Seed Extract which has been shown in clinical studies to raise free testosterone levels
20		2. <u>Television</u>
21	138.	A thirty-second television commercial for Mdrive, available at
22	http://www.	ispot.tv/ad/7ZNs/mdrive, has aired nationally 67 times, including on February 23,
23	2014 at 11:4	8 a.m. PST on NBA TV. The commercial, which also features the GNC logo,
24	states that "I	Mdrive is formulated for guys who crave more free testosterone," and
25	directs view	ers to the website <u>www.Mdrive4men.com</u> for more information.
26		
27		
28		

3. Websites

- 139. The websites www.mdrive4men.com are owned by defendant DreamBrands, and have the same content. The websites (Exh. 33) state that Mdrive "contains a clinically tested ingredient that naturally increases healthy testosterone in the body;" "Testofen's clinical results confirmed a boost in free testosterone levels;" and "Mdrive is the only clinically proven formula."
- 140. Under the heading "MDrive Science," the websites state that "we added a specific fenugreek seed extract . . . to ensure increased healthy normal levels of free testosterone;" that MDrive contains "specific ingredients that have been clinically tested and shown to increase free testosterone;" and that "Testofen's clinical results confirmed a boost in free testosterone levels in men"
- 141. The website www.dreambrands.com is owned by defendant DreamBrands. The website (Exh. 34) states that Mdrive "Naturally Increase[s] Testosterone," "contains a clinically tested ingredient that naturally increases healthy testosterone in the body," and "contains Testofen. A clinical study of Gencor's Testofen revealed that it promoted healthy free testosterone levels in the active group of subjects." The website also states, as to both Mdrive and Mdrive Elite:

Increase Testosterone

Testofen's clinical results confirmed a boost in free testosterone levels in men

G. Test Freak

1. <u>Label and packaging</u>

142. The label and packaging for Test Freak Hybrid Pro-Testosterone Stimulator ("Test Freak") (Exh. 35) state that the product "Increases Free Testosterone," and is "The World's Most Cutting Edge Testosterone-Boosting Formula!" The packaging states that the product "is "Unquestionably the Most Powerful Test Booster Ever Created!" and that the product:

	1
	2
	3
	4
	5
	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0
2	1
2	2
2	3
2	4
2	5
2	6
2	7
2	8

Supplies more TESTOFEN than any other test booster on the market! On its own, TESTOFEN is clinically shown to boost free testosterone levels in humans by an incredible average of 98.8%!

2. Website

143. The website www.pharmafreak.com is owned by defendant PharmaFreak. The website (Exh. 36) states that Test Freak "Helps Increase Free Testosterone! Helps Increase Total Testosterone!", and "Provides clinically researched testosterone-boosting ingredients!"

H. PMD N-TEST 600/Flex Stack

1. Label and packaging

144. The packaging for PMD Flex Stack (Exh. 37), which contains a bottle of PMD N-TEST 600, states:

Natural Testosterone Booster: N-TEST 600 is fully jacked with 600 mg of Testofen, the clinically studied amount necessary to increase free flow testosterone levels up to 98%.*

DYNAMIC RESULTS WITH TESTOFEN!

Clinically Studied* **Testofen**

98% INCREASE IN FREE TESTOSTERONE

*Effect of Testofen on safety, anabolic activity and factors affecting exercise physiology. Copyright by Gencor Nutrients, Inc.

145. The label for PMD N-TEST 600 (Exh. 38) states:

INSANE TESTOSTERONE BOOST

600 mg of **Testofen** Clinically Proven Amount*

Increase Free Testosterone Levels Up to 98%* With 600 mg of Clinically Studied Testofen

*Effect of Testofen on safety, anabolic activity and factors affecting exercise physiology. Copyright 2008 by Gencor Nutrients, Inc.

		2. Website
1	146.	The website <u>www.ndsnutrition.com</u> is owned by defendant NDS. The website
2	(Exh. 39) stat	es:
3 4 5		N-TEST 600 is a strong natural testosterone booster fully loaded with 600 mg of Testofen, the clinically studied amount necessary to increase free testosterone levels up to 98% [†]
6		†Effect of Testofen on safety, anabolic activity and factors affecting exercise physiology. Copyright 2008 by Gencor Nutrients, Inc.
8	I.	NO2 Red Test
9		1. <u>Label</u>
10	147.	The label for NO2 Red Test (Exh. 40) states:
11		NATURALLY BOOST TESTOSTERONE LEVELS
12		WIITH CLINICALLY TESTED INGREDIENTS* 98% INCREASE IN FREE TESTOSTERONE
13		2. Website
14	148.	The website www.mri-performance.com is owned by defendant MRI. The
15	website (Exh.	41) states:
16 17 18		NO2 RED TEST – the scientific, MRI approach to naturally boosting testosterone levels. Through an impressive line-up of powerful, clinically tested ingredients, NO2 RED TEST drives an incredible 98% increase in free testosterone.
19	J.	Ultra T Gold
20		1. <u>Label and Packaging</u>
21	149.	The label and packaging for Ultra T Gold (Exh. 42) state:
22		with clinically studied Testofen
23		ALL-NATURAL FREE TESTOSTERONE BOOSTER
24		Naturally increases free testosterone Clinically tested
26		Are you Looking to Boost Testosterone?
27		Ultra T Gold is a natural solution for boosting free testosterone levels
28		25

	2
	3
	4
	5
	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0
2	1
2	2
2	3
2	4
2	5
2	6
2	7
2	8

The all natural key ingredient in Ultra T Gold was shown in [a] double-blind, placebo controlled, human clinical stud[y] . . . to be a safe and effective way to significantly boost free testosterone levels

2. Website

150. The website www.naturade.com is owned by defendant Naturade. The website (Exh. 43) contains the same representations concerning Ultra T Gold as the label and packaging.

K. Vitali-T-Aid

1. <u>Label and Packaging</u>

151. The label and packaging for Vitali-T-Aid (Exh. 44) state:

BOOST TESTOSTERONE with clinically studied Testofen

- Naturally increases free testosterone
- Clinically tested

Are you looking to Boost Testosterone?

Vitali-T-Aid is a natural solution for boosting free testosterone levels

The all natural key ingredient in Vitali-T-Aid was shown in [a] double-blind, placebo controlled, human clinical stud[y], . . . to be a safe and effective way to significantly boost free testosterone levels

152. The label and packaging for Vitali-T-Aid Energy (Exh. 45) state:

with clinically studied Testofen

• Supports natural increases of free testosterone in men

Are you Looking to Help Boost Free Testosterone? Vitali-T-Aid [ENERGY] is a solution for supporting free testosterone levels

Clinically Studied Ingredient

The all natural key ingredient in Vitali-T-Aid [ENERGY] was shown in [a] double-blind, placebo controlled, human clinical stud[y], . . . to be a safe and effective way to significantly help boost free testosterone levels

2. Websites

153. The website www.naturade.com is owned by defendant Naturade. The website contains the same representations concerning Vitali-T-Aid (Exh. 46) and Vitali-T-Aid Energy (Exh. 47) as the label and packaging.

3. <u>Television and Print Advertising</u>

- 154. A press release issued by Naturade (Exh. 48) stated that "Vitali-T-Aid is being launched with a multi-million dollar direct response television and print advertising campaign . "
- 155. A television commercial for Vitali-T-Aid, available at http://www.youtube.com/watch?v=XgiFqcl5dnA, states that Vitali-T-Aid "will boost your free testosterone levels Clinical tests have shown that Vitali-T-Aid significantly increases free testosterone levels"

L. Testoril

1. Label and packaging

156. The label and packaging for Testoril (Exh. 49) state that it is a "Clinically Proven Testosterone Booster With Clinically Studied Testofen." A package insert states that "You've just purchased the world's #1 testosterone booster. We guarantee it." The package insert states that "Testoril ingredients have been scientifically researched and clinically tested."

2. Website

157. The website www.testoril.com is owned by defendant Premium Nutraceuticals. The website (Exh. 50) states:

Clinically Proven THE STRONG, POWERFUL & Effective Testosterone Booster

Most importantly, our formulators developed the Testoril blend with the clinically proven dosage of Testofen

A DAILY SUPPLEMENT OF TESTORIL CAN HELP BOOST YOUR TESTOSTERONE NATURALLY!

1 2		Unlike other over the counter testosterone supplements, the featured ingredient in Testoril, Testofen, has been clinically proven to increase testosterone production.
3		STUDIES AND TESTS HAVE SHOWN THAT TESTOFEN THE FEATURED INGREDIENT IN TESTORIL CAN PRODUCE EFFECTIVE RESULTS!
5		Consider this: Testoril has been formulated based on the most current emerging medical research and clinical trials on the effects that dietary supplementation has on aging and features Testofen
7		which is supported by clinical studies. A Daily Supplement of Testoril Can Help Boost Your Testosterone Naturally
9		Testoril has been formulated with Testofen to help your body begin releasing higher levels of your own, naturally produced hormones like free testosterone.
11		Testoril has been formulated to help men suffering with Testosterone deficiency take that first step in reclaiming their life.
13		Male Testosterone deficiency is REAL and there's something you can do about it. You have nothing to lose and everything to gain!
14 15 16		TESTOFEN (Standardized Fenugreek Seed Extract) You are probably asking: "How do I safely increase my free testosterone levels?" Well researched testosterone boosters, like Testoril, can be the answer.
17		To view the results of the latest clinical study of Testofen please Click Here To Review This Clinical Study.
18 19 20		Testoril is backed by smart science, not fly-by-night data. There is no reason to risk your health by using disreputable testosterone boosters with cheap ingredients. It's just not worth it!
21		Proven Ingredients That Work Clinically Studied for Ultimate Performance
22	158.	Visitors to the website who "Click Here To Review This Clinical Study" are
23	taken to Geno	cor's 2006 "Testofen Human Clinical Trial" report.
24	IX. GNC	's Central Role In Marketing "Testosterone Boosters"
25	Α.	GNC's Dominant Role in the Supplements Industry
26	159.	In its most recent annual report, GNC describes itself as "the leading global
27 28	specialty reta	iler of health and wellness products, including vitamins, minerals and herbal
-		

27

28

supplement products, sports nutrition products and diet products." As of December 31, 2013, GNC operated 3,342 company-owned stores in the United States and Canada, and there were another 3,036 franchise locations in the United States.

- 160. In 2013, domestic retail sales at GNC's company-owned stores and its website, www.gnc.com totaled over \$1.7 billion, including \$765 million in sports nutrition products, GNC's largest product category, which includes most of the products sold by GNC containing Testofen.
- 161. GNC describes its dominant position in the marketplace, its close relationships with supplement manufacturers, and the trust and confidence placed in GNC by its customers, as follows:

We believe that the strength of our GNC brand, which is distinctively associated with health and wellness, combined with our stores and online channels, gives us broad access to consumers and uniquely positions us to benefit from the favorable trends driving growth in the nutritional supplements industry and the broader health and wellness sector.

Our network of domestic retail locations is approximately ten times larger than the next largest United States specialty retailer of nutritional supplements and provides a leading platform for our vendors to distribute their products to their target consumers. Our close relationships with our vendor partners have enabled us to negotiate first-to-market opportunities. In addition, our in-house product development capabilities enable us to offer our customers proprietary merchandise that can only be purchased through our locations or through GNC.com. Because the nutritional supplement consumer often requires knowledgeable customer service, we also differentiate ourselves from mass and drug retailers with our well-trained sales associates who are aided by instore technology. We believe that our expansive retail network, differentiated merchandise offering and quality customer service result in a unique shopping experience that is distinct from that of our competitors.

We believe we distinguish ourselves from mass and drug retailers with our well-trained sales associates, who offer educated service and trusted advice.

B. GNC's Exclusive Arrangements With Its Vendor Partners

162. Among the "first-to-market opportunities" that GNC has negotiated through its "close relationships" with its "vendor partners" are three of GNC's best-selling products, Nugenix, Troxyphen, and High T.

1. Nugenix

163. An August 16, 2012 press release (Exh. 51) announced that:

Direct Digital, LLC . . . recently announced the launch of NUGENIX, an all-new, natural testosterone booster

NUGENIX, a first-of-its-kind product in the Men's Vitality category, will initially be offered exclusively at GNC, and is already available at GNC.com.

Based upon the on-going successful partnership between GNC and Direct Digital, the exclusive launch of NUGENIX within GNC stores is the perfect platform to present such a revolutionary new product offering.

164. A September 11, 2012 press release (Exh. 52) announced that:

NUGENIX Natural Testosterone Booster Tops Men's Vitality Category Sales on GNC.com

NUGENIX, a first-of-its kind men's wellness product that naturally boosts testosterone, . . . recently launched online and was GNC.com's top-selling Men's Vitality product for the month of August 2012.

Despite having only been available for a matter of weeks, NUGENIX has proven so popular, it has completely sold-out online via its exclusive web retailers. However, it is once again available in its various e-tail venues and will soon be offered in nearly 5,000 U.S.-based GNC retail locations.

"The decision to launch on GNC.com has definitely proven to be the right one. NUGENIX is GNC's top online seller within the Men's Vitality category despite limited launch distribution. In fact, it is a top-seller and will not even reach all their retail locations until later this month," stated Brandon Adcock, cofounder and president of Direct Digital, LLC, the developer and marketer of NUGENIX. "Through our ongoing partnership... we've been confident since day one that GNC was the ideal retail channel to educate the core consumer regarding the numerous benefits associated with every Direct Digital nutritional support product. We are thrilled with the overwhelming response and record-breaking sales NUGENIX has experienced in its first month of existence."

	1
	2
	3
	4
	5
	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0
2	1
2	2
2	3
2	4
2	5

165. According to Direct Digital:

Nugenix was the number one selling Men's Vitality product in GNC during 2013 and continues this year [2014] to be the top selling Men's Vitality product in GNC.

- Awards for 2013, recognizing their commitment to achieving customer satisfaction through innovative sports and wellness products," which GNC describes as "our opportunity to recognize publicly their contributions to innovation, product quality and consumer information" (Exh. 53.) In the category of "Product Information," the award went to Nugenix.
- 167. In GNC's list of award recipients, the word "Nugenix" hyperlinks to the following product information (Exh. 54):

How to Boost Your Free Testosterone: GNC's #1 Selling & Award Winning Free Testosterone Booster

On February 19th, 2014 GNC the nation's largest specialty vitamin retailer announced its annual product award winners. GNC singled out less than ten companies and products for special awards.

One award winner in particular received strong praise. Nugenix a free testosterone booster and the top selling product in the Men's Vitality category.

Over the years, any number of pills, potions, and gels have claimed to work wonders for men's free testosterone. In reality, few of these options do any good.

Nugenix, which triggers your body into increasing its levels of free testosterone, helped break the stereotype that free testosterone boosters are only for hardcore bodybuilders. GNC stores secured the exclusive rights to Nugenix's US launch and within three months it was one of the top selling vitality supplements in the entire GNC chain.

The key ingredient is Testofen which is made from the rare Fenugreek plant. Testofen has been shown in clinical trials to boost free testosterone levels

GNC stores secured the exclusive retail rights to Nugenix's US launch and it's carried in GNC stores nationwide. Click Here >

168. Clicking on "Click Here" redirects visitors to the website,

https://www.nugenix.com/trial/ (Exh. 55) which states, under the GNC logo:

26

27

"It is always a pleasure to deliver these well-deserved awards that our vendor partners work so hard to achieve," said Tom Dowd, GNC Executive Vice President, and Chief Merchandising Officer & General Manager. "This is our opportunity to recognize publicly their contributions to . . . consumer information"

169. After being redirected to the website https://www.nugenix.com/trial/, visitors are presented with a "pop-up" window with the GNC logo (Exh. 56), which states:

NUGENIX PRODUCTS AVAILABLE AT

GNC Live Well SHOP NATIONWIDE OR AT GNC.COM

Testosterone Booster

SHOP NOW

- 170. Clicking on "SHOP NOW" redirects visitors to the GNC website, http://www.gnc.com, to purchase Nugenix.
- 171. A 60-second television commercial for Nugenix, available at http://www.ispot.tv/ad/7dIG/nugenix, has aired nationally 6,967 times, including on April 15, 2014 at 5:23 a.m. PST on Smithsonian. The commercial is co-branded with GNC, and directs viewers to the website "TRYNUGENIX.COM" (Exh. 54), which contains the same product information and links presented *supra*.
- 172. A series of mass email advertisements for Nugenix sent by Direct Digital, all of them co-branded with GNC (Exh. 120), state:

The Truth About Testosterone

We hear and see ads all of the time about male products that don't explain what they really are.

What if there was a male product that was backed by real science? What if that same product just happened to be GNC's #1 selling vitality product?

Nugenix is . . . carefully blended to help boost the all-important free testosterone.

- 173. Another series of mass email advertisements for Nugenix sent by Direct Digital, all of them co-branded with GNC (Exh. 121), state:
 - Clinical studies support award-winning free testosterone booster

Nugenix Free Testosterone Booster is the top-selling men's vitality

	1
	2
	3
	4
	5
	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0
2	1
2	2
2	3
2	4
2	5
2	6
2	7
2	8

product and an award winning supplement at GNC. The key ingredient in Nugenix is Testofen

Testofen has been shown in clinical trials to Boost free testosterone levels

174. Another series of mass email advertisements for Nugenix sent by Direct Digital (Exh. 122) state that Nugenix is available "EXCLUSIVELY AT GNC," and that "The key clinically researched ingredient, Testofen, is what gives Nugenix an edge over other products that claim to increase free testosterone."

2. Troxyphen

175. A February 23, 2013 press release (Exh. 57) announced that:

Troxyphen the first product to be launched under truDERMA's new pūrFORMANCE line for men is available now exclusively at GNC stores nationwide, http://www.gnc.com.

Troxyphen naturally and significantly increases your base line testosterone levels

"Troxyphen is a natural testosterone booster for men We are thrilled to introduce Troxyphen exclusively at GNC.

Troxyphen is available at a GNC store near you or online at http://www.gnc.com

176. As set forth above, a nationwide radio commercial for Troxyphen, which has aired thousands of times, states that "Troxyphen is GNC's best-selling, 100% natural and most powerful testosterone booster," and that "Troxyphen is available nationwide at GNC stores." The commercial also directs listeners to the website "stoplowt.com" or "raisemytest.com" (which is redirected to www.troxyphen2.com), which are co-branded with GNC.

3. High T

177. An October 10, 2011 press release (Exh. 58) states:

Kingfisher Media . . . today announced the introduction of its all natural testosterone booster High T through GNC stores nationwide.

The initial launch will consist of 800 stores with an additional 2,000 stores by end of Q1 2012.

"We are very pleased to partner with GNC in High T's introduction to the market and we believe, given their reputation

for high quality products and cutting edge sports science, that GNC is the perfect venue for High T," said a spokesperson representing Kingfisher Media. "GNC's customer base – health-conscious individuals who are savvy and informed about supplement quality – is the ideal market for High T."

4. PMD N-TEST 600/Flex Stack

178. PMD N-TEST 600 and PMD Flex Stack are sold exclusively through GNC.

5. NO2 Red Test

179. NO2 Red Test is sold exclusively through GNC.

C. GNC'S Dominant Role in the Marketing and Sale of "Testosterone Boosters"

180. GNC markets and sells the following nineteen products containing Testofen as clinically proven to increase free testosterone levels, at the following retail prices:

Nugenix	\$69.99
Troxyphen	\$59.99
Troxyphen Elite	\$69.99
Ageless Male	\$44.99
Test X180	\$69.99
Test X180 Alpha	\$139.99
Test X180 Ignite	\$79.99
Stack Factor 2 With Test X180	\$139.98
High T	\$49.99
High T Senior	\$59.99
High T Black	\$69.99
High T Caffeine Free	\$69.99
Mdrive	\$69.99
Mdrive Elite	\$79.99
Test Freak	\$79.99
PMD N-TEST 600	\$119.99
PMD Flex Stack	\$199.99
NO2 Red Test	\$79.99

Ultra T Gold \$39.99

- 181. The GNC Suppliers also make these products available on their respective websites, at the same retail prices, plus shipping.
- 182. GNC and its "vendor partners" market these products through a variety of channels and co-branding arrangements, including television, radio, websites, direct mail, email, and point-of-sale displays at GNC retail locations.

1. Retail Displays

- 183. GNC retail locations have standardized point-of-sale displays, including shelf signage, floor displays, and checkout displays.
- 184. Each GNC retail location has a "Men's Health" section (Exh. 59), located in a high-visibility position within the store. The Men's Health section displays a sign (Exh. 60) entitled "Testosterone Support," featuring the image of Frank J. Costa, M.D., a "Member of the GNC Medical Advisory Board" and "World-Renowned Urologist and Expert in Prostate Health."
- 185. The Men's Health section displays most of the products sold by GNC containing Testofen, including, without limitation, Nugenix, Ageless Male, and the full range of Test X180 and High T products. Signage identifies certain products, such as High T, as a "Best Seller."
- 186. Each GNC retail location has a "Newest Latest Greatest" section (Exh. 61), located in a high-visibility position within the store. The Newest Latest Greatest section features a number of products containing Testofen, including, without limitation, Nugenix, Troxyphen, and Test X180, High T, and Mdrive products.
- 187. GNC retail locations also display products containing Testofen in other locations within the store (Exh. 62), including, without limitation, Nugenix, Troxyphen, Test Freak, and Test X180, High T, and Mdrive products.

188. Each GNC retail location has a "Hot New Products" display (Exh. 63) located at the checkout counter. The Hot New Products display features products containing Testofen, including, without limitation, High T and Test X180 products.

189. GNC retail locations also feature floor and hanging shelf displays for products containing Testofen, including a floor display for "NUGENIX NATURAL TESTOSTERONE BOOSTER" featuring the GNC logo (Exh. 64), hanging shelf displays for Test X180 Alpha (Exh. 65), and floor and shelf displays for High T products.

190. An August 6, 2012 press release (Exh. 66) states:

Kingfisher Media . . . today announced that GNC will be introducing new point of sale displays nationally to promote the High T family of products.

The Point of Purchase (POP) displays consist of two distinct units: a sleek black upright unit for the *Ultimate Stack* – a triple combination of Black High T, High G, and High T Gel – and a gravity feed rack for High T White. The High T White gravity feed racks will be placed in 4,000 total stores while the Ultimate Stack displays will be found in 1,400 locations. Both units have been met with enthusiasm from customers.

"These displays are an additional step in cementing High T's brand awareness among GNC customers," said D. William Pettigrew, Director of Sales and Marketing for Kingfisher Media. "Our point of sale displays will be placed in prime locations within GNC's stores to highlight the High T name. This roll-out represents GNC's support of and commitment to our brand."

2. Mailers

191. GNC regularly sends mailers to its customers for whom it has postal addresses advertising products containing Testofen (Exh. 67), including, without limitation, Nugenix, Troxyphen, Test X180, and High T products.

3. Email

192. GNC sends email messages to its customers for whom it has email addresses advertising products containing Testofen (Exh. 112), including, without limitation, Nugenix, Troxyphen, Test X180, and High T products.

	1
	2
	3
	4
	5
	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0
2	1
2	2
2	3
2	4
2	5
2	6

28

D. <u>GNC's Representations Concerning Its Vendor Partners' "Testosterone Boosters"</u>

1. Nugenix

193. On its websites, www.gnc.com (Exh. 68) and www.LuckyVitamin.com (Exh. 69), GNC states that "Nugenix Natural Testosterone Booster is an all natural Testosterone booster that contains clinically studied ingredients that are proven to boost free testosterone levels"

2. <u>Troxyphen</u>

194. On its websites, www.gnc.com (Exh. 70) and www.LuckyVitamin.com (Exh. 71), GNC states that Troxyphen contains "Ingredients Shown to Help Raise Testosterone," and that Troxyphen "naturally and significantly increase[es] your base line Testosterone levels" On its websites, www.gnc.com (Exh. 72) and www.LuckyVitamin.com (Exh. 73), GNC states that Troxyphen Elite is "A Powerful Free Testosterone Booster" with "INGREDIENTS SHOWN TO HELP: Raise Free Test Levels" that "naturally and significantly increase[es] your base line Testosterone levels."

3. Ageless Male

195. On its websites, <u>www.gnc.com</u> and <u>www.LuckyVitamin.com</u> (Exh. 74), GNC states that:

Ageless Male is made with a standardized extract called Testofen, which is clinically-tested ingredient derived from the fenugreek herb. A double-blind, randomized, placebo-controlled human clinical study on Testofen has shown it can significantly help boost free testosterone in men.

The key ingredient in Ageless Male has been shown in published human research to help significantly boost free testosterone levels .

What is the key ingredient in Ageless Male?

It's called Testofen, which is a natural and clinically-tested ingredient derived from the fenugreek herb. A double-blind, randomized, placebo-controlled human clinical study on Testofen has shown it can significantly help boost free testosterone in men .

. . .

4. Test X180

196. On its websites, <u>www.gnc.com</u> (Exh. 75) and <u>www.LuckyVitamin.com</u> (Exh. 76), GNC states that:

The experts at Force Factor carefully formulated Test X180 to provide the boost that every man needs. By naturally raising your levels of free testosterone

Each serving of Test X180 contains clinically researched levels of Testofen Testofen is the well-known, effective compound your body needs to combat natural testosterone decline.

There's no need to take a chance on your health with untested, risky ingredients. Look and feel confident while you perform at your peak with the trusted ingredients in Test X180.

197. On its websites, www.gnc.com (Exh. 77) and www.LuckyVitamin.com (Exh. 78), GNC states that "The Force Factor team perfected the Test X180 Alpha formula with one of the only natural ingredients clinically demonstrated to increase free testosterone levels: Testofen," and that "the natural ingredient Testofen is clinically demonstrated to raise your body's free testosterone levels." On its websites, www.gnc.com (Exh. 79) and www.LuckyVitamin.com (Exh. 80), GNC states that "Test X180 Ignite was developed to be the ultimate all-in-one free testosterone booster, using safe, trusted ingredients backed in real science. Test X180 Ignite is fueled by Testofen, a natural fenugreek seed extract," and that "Testofen helps raise your body's levels of free testosterone"

5. High T

198. On its websites, www.gnc.com (Exh. 81) and www.LuckyVitamin.com (Exh. 82), GNC describes High T as an "ALL NATURAL TESTOSTERONE BOOSTER" that "has been clinically proven to boost free Testosterone levels;" states that "High T has been clinically proven to boost free Testosterone levels;" and states that "Testofen is an all natural extract that has been clinically proven in human studies to boost Testosterone levels " On its websites, www.gnc.com (Exh. 83) and www.LuckyVitamin.com (Exh. 84), GNC describes High T Black as a "Testosterone Booster." On its websites, www.gnc.com (Exh. 85) and

1	www.Lucky\	Vitamin.com (Exh. 86), GNC describes High T Caffeine Free as a "Testosterone	
2	Booster" that "has been scientifically formulated to help Testosterone levels"		
3		6. <u>Mdrive</u>	
4	199.	On its websites, www.gnc.com (Exh. 87) and www.LuckyVitamin.com (Exh.	
5	88), GNC rep	resents that:	
6 7		Ingredients in M-Drive have been shown to increase testosterone levels Developed with intensive research, M-Drive uses the most effective natural ingredients.	
8		*M-Drive contains Testofen - a Fenugreek Seed Extract clinically proven to promote healthy free testosterone levels	
10		*A clinical study of Testofen revealed that it promoted healthy free testosterone levels in the active group of subjects by 98%.	
11	200.	On its websites, www.gnc.com (Exh. 89) and www.LuckyVitamin.com (Exh.	
12	90), GNC des	scribes Mdrive Elite as "an Energizing Testosterone Booster" that "contains the	
13	same trusted	premium compounded formula as the original Mdrive. It still naturally increases	
14	healthy free to	estosterone levels." GNC states that the product contains:	
15		Clinically Tested Ingredients At the Clinical Levels.	
17 18		• Increase Testosterone Testofen's clinical results confirmed a boost in free testosterone levels in men	
19		Clinically Proven IngredientsIncrease Free Testosterone	
20		 Testofen Fenugreek is clinically proven to increase healthy free testosterone. 	
22		7. <u>Test Freak</u>	
23	201.	On its website, www.gnc.com (Exh. 91), GNC states that Test Freak contains:	
24		100% Clinically-Proven and Organically Altered Pro Testosterone	
25		CompoundsIncreases Free Testosterone!Increases Total Testosterone!	
2627		The World's Most Cutting Edge Testosterone-Boosting Formula!	
28			

	1
	2
	3
	4
	5
	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0
2	1
2	2
2	3
2	4
2	5
2	6
2	7
2	8

TEST FREAK is hands-down one of the strongest testosterone boosters legally available! It has been created specifically for hardcore bodybuilders and extreme athletes who are looking to crank testosterone levels to the max! . . . TEST FREAK's one-of-a-kind formula contains clinically-proven dosages of the most heavily researched testosterone-boosting compounds

8. PMD N-TEST 600/Flex Stack

202. On its website, www.gnc.com (Exh. 92), GNC states that PMD N-TEST 600, included in PMD Flex Stack, is a "Natural Testosterone Booster" which "is fully jacked with 600 mg of Testofen, clinically studied amount necessary to increase free flow testosterone levels up to 98%. . . . N-TEST 600 increases testosterone levels naturally"

9. NO2 Red Test

203. On its websites, www.gnc.com (Exh. 93) and www.LuckyVitamin.com (Exh. 94), GNC states that:

NO2 Red Test will naturally boost testosterone levels with clinically tested ingredients.

• 98% Increase in Free Testosterone

NO2 Red Test - the scientific, MRI approach to naturally boosting testosterone levels. Through an impressive line-up of powerful, clinically tested ingredients, NO2 Red Test drives an incredible 98% increase in free testosterone.

10. Ultra T Gold

204. On its website, www.LuckyVitamin.com (Exh. 95), GNC states that:

Ageless Foundation Ultra T Gold All-Natural Free Testosterone Booster is a natural solution for increasing free testosterone levels .

Ageless Foundation Ultra T Gold All-Natural Free Testosterone Booster contains clinically studied levels of Testofen. Ageless Foundations Testofen is a natural solution for boosting free testosterone levels In human trials, Testofen was shown to:

- Increase free testosterone levels by 98%
- 205. The foregoing statements appear by default on the www.gnc.com and <a href="www.gnc.

	1
	2
	3
	4
	5
	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0
2	1
2	2
2	3
2	4
2	5
2	6
2	7

206. On the website, www.gnc.com, there are five tabs on each such product page, the third of which is "Health Notes." Clicking on the "Health Notes" tab on the product pages for Troxyphen, Troxyphen Elite, Test X180, Test X180 Alpha, Test X180 Ignite, High T, High T Black, High T Black Caffeine Free, Mdrive, Mdrive Elite, and Test Freak presents the following disclaimer:

Disclaimer: This scientific independent research is provided by Aisle7 and is for informational use only. GNC provides this information as a service but does not endorse it. Likewise, Aisle7 does not recommend or endorse any specific products.

207. After clicking on "I accept these terms," the website displays the following information about Troxyphen (Exh. 96), Troxyphen Elite (Exh. 97), Test X180 (Exh. 98), Test X180 Alpha (Exh. 99), Test X180 Ignite (Exh. 100), High T (Exh. 101), High T Black (Exh. 102), High T Caffeine Free (Exh. 103), Mdrive (Exh. 104), Mdrive Elite (Exh. 105), and Test Freak (Exh. 106):

Natural Testosterone Support

In men, testosterone levels peak in young adulthood and decline over time. A number of supplements are marketed as natural testosterone support, **though these effects have not been demonstrated in clinical research** [emphasis added].

E. GNC's Watered-Down Representations Concerning Its Own Products Containing Testofen

208. In addition to the marketing and sale of "testosterone boosters" manufactured by its vendor partners, GNC manufactures, markets, and sells its own products containing Testofen, including GNC Pro Performance Hybrid Test Complex ("Hybrid Test Complex"), GNC Beyond Raw Re-Test Hardcore Anabolic Enhancer ("Re-Test"), and GNC Preventive Nutrition Healthy Testosterone Formula ("Healthy Testosterone Formula").

209. In its most recent annual report, GNC explains that:

We have an internal research and development group that performs scientific research on potential new products and enhancements to existing products, in part to assist our product development team in creating new products, and in part to support claims that may be made as to the purpose and function of the product.

210. The GNC Medical Advisory Board (Exh. 107):

is comprised of Board Certified and world-renowned physicians who aid in the creation and ongoing development of GNC products. Using their years of medical experience, in-depth knowledge of the latest advancements in medical research and nutritional supplementation, . . . the Board provides invaluable insight that keeps GNC on the forefront of product innovation and delivering on our commitment to helping you LIVE WELL.

211. The label for GNC's Healthy Testosterone Formula (Exh. 108) states that:

GNC Preventive Nutrition Products have been scientifically developed utilizing the expertise of the GNC Medical Advisory Board. . . . This line of products is precisely formulated to provide clinical strength ingredients and additional nutrients that address key health concerns.

DEVELOPED WITH AND ENDORSED BY GNC MEDICAL ADVISORY BOARD ADVANCED KNOWLEDGE FOR BETTER HEALTH

The GNC Medical Advisory Board utilizes their in-depth medical knowledge and experience to aid in the creation and ongoing development of GNC products

- 212. Unlike the products containing Testofen manufactured by its vendor partners, GNC does *not* represent that any of its *own* products containing Testofen are clinically proven to increase free testosterone levels.
- 213. GNC represents that its Hybrid Test Complex (Exh. 109) "Helps to Support Testosterone Levels," and contains "600 mg Testofen Fenugreek to Trigger Anabolic Factors."
- 214. GNC represents that its Re-Test (Exh. 110) "supports healthy testosterone levels with a clinically advanced anabolic primer."
- 215. GNC represents that its Healthy Testosterone Formula is "designed to support testosterone . . . levels that decline with age," and "contains clinically studied ingredients" including "Testofen from fenugreek seed extract, clinically shown to improve sexual health . . . "

4

25

X. Defendants' Knowledge That Testofen Has Not Been Clinically Proven to Increase Free Testosterone Levels

A. **GNC**

- GNC's "watered-down" claims regarding its own products containing Testofen 216. are compelling evidence that the GNC Medical Advisory Board has concluded that Testofen has *not* been clinically proven to increase free testosterone levels.
- GNC's statements on its website, www.gnc.com, that Troxyphen, Troxyphen Elite, Test X180, Test X180 Alpha, Test X180 Ignite, High T, High T Black, High T Black Caffeine Free, Mdrive, Mdrive Elite, and Test Freak "are marketed as natural testosterone support, though these effects have not been demonstrated in clinical research" (para. 207, *supra*) are conclusive evidence that GNC is fully aware that Testofen has *not* been clinically proven to increase free testosterone levels.

В. **Gencor Defendants**

- 218. The Gencor Defendants' deliberate manipulation of the identification of the primary and secondary variables in the Testofen Study is compelling evidence that the Gencor Defendants are fully aware that Testofen has *not* been clinically proven to increase free testosterone levels.
- 219. On November 21, 2013, the Gencor Defendants and Direct Digital received Professor Jewell's unredacted report (Exh. 5) concluding that Testofen has *not* been clinically proven to increase free testosterone levels, and that Gencor's claims to the contrary are *false*. Over a year later, the Gencor Defendants continue to market and sell Testofen for inclusion in "Testosterone Boosters" based on their false representation that Testofen has been clinically proven to increase free testosterone levels.

C. **Direct Digital**

A May 23, 2013 press release (Exh. 111) states that: 220.

> Direct Digital, LLC . . . is pleased to announce it has selected and partnered with world-renowned physician, Dr. David Katz. Dr. Katz will join the organization as its Chief Scientific and Medical

 Advisor. Direct Digital is the creator of such leading supplement brands as . . . Nugenix Natural Testosterone Booster

Dr. Katz serves as the Director and Co-Founder of the Yale Prevention Research Center, the Director of Integrative Medicine at Griffin Hospital in Derby, CT, the President Elect of the American College of Lifestyle Medicine, and is the President and Founder of the Turn the Tide Foundation. Dr. Katz is also a Fellow of the American College of Preventive Medicine (FACPM), and the American College of Physicians (FACP).

As Charlotte's fastest growing private company in 2012 (as recognized by the Charlotte Business Journal), Direct Digital understands the significance of developing quality products, backed by solid science. By bringing Dr. Katz on board to consult regarding current and future product formulations, it was yet another way the company could demonstrate its commitment to the highest standards of business and the most significant levels of research and development.

"[D]evising the best products requires hard work, diligent attention to the details of science, and a commitment to a cautious approach that puts safety first. I've been very impressed that Direct Digital embodies just such principles. I am delighted to serve in a role that will allow me to offer candid, evidence-based guidance in the service of developing and making available products that combine safety with the greatest possible therapeutic effects," said Dr. Katz.

221. Notwithstanding Direct Digital's purported "diligent attention to the details of science" and "evidence-based guidance," a year following the receipt of Professor Jewell's report, it continues to create and disseminate *new* advertisements falsely stating that "Testofen has been shown in clinical trials to boost free testosterone levels" (para. 167, *supra*). *See also* para. 172-174.

XI. Plaintiffs' Purchases of "Testosterone Boosters"

- 222. Plaintiff Ryan purchased seven bottles of Nugenix from the website www.nugenix.com, at the retail price, between February 2014 and August 2014. In making these purchases, Ryan relied on the misrepresentations set forth in paragraphs 108-111 above.
- 223. Plaintiff Ryan purchased four bottles of Test X180 Ignite from the website www.forcefactor.com, at the retail price, between July 2014 and October 2014. In making these purchases, Ryan relied on the misrepresentations set forth in paragraphs 129-130 above.

- 224. Plaintiff Garza purchased a bottle of Nugenix at a GNC retail location in Gilroy, California, at the retail price, in 2013. In making this purchase, Garza relied on the misrepresentations set forth in paragraphs 108-110 above.
- 225. Plaintiff Garza purchased a bottle of Ageless Male at a GNC retail location in Gilroy, California, at the retail price, in 2013. In making this purchase, Garza relied on the misrepresentations set forth in paragraph 116 above.
- 226. Plaintiff Aguero purchased a bottle of Test X180 at a GNC retail location in Apple Valley, California, at the retail price, in approximately July 2014. In making this purchase, Aguero relied on the misrepresentations set forth in paragraphs 127-128 above.
- 227. Plaintiff Aguero purchased a bottle of High T at a Walgreens in Hesperia, California, at the retail price, in approximately June 2014. In making this purchase, Aguero relied on the misrepresentations set forth in paragraph 131 above.
- 228. Plaintiff Cowans purchased a bottle of NO2 Red Test at a GNC retail location in Fresno, California, at the retail price. In making this purchase, Cowans relied on the misrepresentations set forth in paragraph 147 above.
- 229. Plaintiff Cowans purchased a bottle of Vitali-T-Aid at the retail price of \$39.99. In making this purchase, Cowans relied on the misrepresentations set forth in paragraph 151 above.
- 230. Plaintiff Erion purchased two bottles of Test Freak at a GNC retail location in Chico, California, at the retail price, in July 2014. In making these purchases, Erion relied on the misrepresentations set forth in paragraph 142 above.
- 231. Plaintiff Ruhnke purchased two bottles of PMD N-TEST 600 at a GNC retail location in Mission Viejo, California, at the retail price. In making these purchases, Ruhnke relied on the misrepresentations set forth in paragraph 145 above.
- 232. Plaintiff Korves purchased three boxes of Testoril from the website www.testoril.com, at the retail price of \$84.99 each, in approximately July 2014. In making

these purchases, Korves relied on the misrepresentations set forth in paragraphs 156-157 above.

- 233. Plaintiff Flores purchased two bottles of Mdrive at a GNC retail location in Santa Cruz, California, at the retail price, in August 2014 and September 2014. In making these purchases, Flores relied on the misrepresentations set forth in paragraph 134 above.
- 234. Plaintiff Berger purchased a bottle of Nugenix at a GNC retail location in Los Angeles, California, at the retail price, in early 2013. In making this purchase, Berger relied on the misrepresentations set forth in paragraphs 108-110 above.
- 235. Plaintiff Torres purchased a bottle of Troxyphen at a GNC retail location in Phoenix, Arizona, at the retail price, in early 2014. In making this purchase, Torres relied on the misrepresentations set forth in paragraph 112 above.
- 236. Plaintiff Torres purchased a bottle of Troxyphen Elite at a GNC retail location in Phoenix, Arizona, at the retail price, in early 2014. In making this purchase, Torres relied on the misrepresentations set forth in paragraph 113 above.
- 237. Plaintiff Torres purchased a bottle of High T at a GNC retail location in Phoenix, Arizona, at the retail price, in early 2014. In making this purchase, Torres relied on the misrepresentations set forth in paragraph 131 above.
- 238. Plaintiff Torres purchased a bottle of High T Senior at a GNC retail location in Phoenix, Arizona, at the retail price, in early 2014. In making this purchase, Torres relied on the misrepresentations set forth in paragraph 131 above.
- 239. Plaintiff Baker purchased a bottle of Nugenix at a GNC retail location in Bloomsburg, Pennsylvania, at the retail price, in the fall of 2012. In making this purchase, Baker relied on the misrepresentations set forth in paragraphs 108-110 above.
- 240. Plaintiff Baker purchased a bottle of Ageless Male at a GNC retail location in Bloomsburg, Pennsylvania, at the retail price, in early 2013. In making this purchase, Baker relied on the misrepresentations set forth in paragraph 116 above.

	1
	2
	3
	4
	5
	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0
2	1
2	2
2	3
2	4
2	5
2	6
2	7
2	8

241. Plaintiff Baker purchased a bottle of High T Black at a GNC retail location in Wyomissing, Pennsylvania, at the retail price, in early 2013. In making this purchase, Baker relied on the misrepresentations set forth in paragraph 131 above.

CLASS ACTION ALLEGATIONS

- 242. Plaintiffs bring this action on behalf of themselves and a Class, defined as: All persons who purchased any of the following products (a "Testosterone Booster"):
 - Nugenix
 - Troxyphen
 - Troxyphen Elite
 - Ageless Male containing Testofen
 - Test X180
 - Test X180 Alpha
 - Test X180 Ignite
 - Stack Factor 2 With Test X180
 - High T
 - High T Senior
 - High T Black
 - High T Caffeine Free
 - Mdrive
 - Mdrive Elite
 - Test Freak
 - PMD N-TEST 600
 - PMD Flex Stack
 - NO2 Red Test
 - Ultra T Gold
 - Vitali-T-Aid
 - Vitali-T-Aid Energy

Testoril

- 243. Plaintiffs reserve the right to supplement this list to include additional or subsequently-introduced products containing Testofen.
- 244. Plaintiffs Garza, Aguero, Cowans, Erion, Ruhnke, Flores, Berger, Torres, and Baker also bring this action on behalf of a GNC Subclass, defined as all persons who purchased any Testosterone Booster from GNC.
- 245. Plaintiffs Ryan, Garza, Berger, and Baker also bring this action on behalf of a Nugenix Subclass, defined as all persons who purchased Nugenix.
- 246. Plaintiffs Garza and Baker also bring this action on behalf of an Ageless Male Subclass, defined as all persons who purchased Ageless Male.
- 247. Plaintiff Torres also brings this action on behalf of a Troxyphen Subclass, defined as all persons who purchased Troxyphen or Troxyphen Elite.
- 248. Plaintiffs Ryan and Aguero also bring this action on behalf of a Test X180 Subclass, defined as all persons who purchased Test X180, Test X180 Alpha, Test X180 Ignite, or Stack Factor 2 With Test X180.
- 249. Plaintiffs Aguero and Torres also bring this action on behalf of a High T Subclass, defined as all persons who purchased High T, High T Senior, High T Black, or High T Caffeine Free.
- 250. Plaintiff Flores also brings this action on behalf of an Mdrive Subclass, defined as all persons who purchased Mdrive or Mdrive Elite.
- 251. Plaintiff Cowans also brings this action on behalf of a Naturade Subclass, defined as all persons who purchased Vital-T-Aid, Vitali-T-Aid Energy, or Ultra T Gold.
- 252. Plaintiff Cowans also brings this action on behalf of an NO2 Red Test Subclass, defined as all persons who purchased NO2 Red Test.
- 253. Plaintiff Ruhnke also brings this action on behalf of a PMD Subclass, defined as all persons who purchased PMD N-TEST 600 or PMD Flex Stack.

- 254. Plaintiff Erion also brings this action on behalf of a Test Freak Subclass, defined as all persons who purchased Test Freak.
- 255. Plaintiff Korves also brings this action on behalf of a Testoril Subclass, defined as all persons who purchased Testoril.
- 256. Plaintiff Torres also brings this action on behalf of an Arizona Subclass, defined as all Class members who purchased any Testosterone Booster in the State of Arizona.
- 257. Plaintiff Baker also brings this action on behalf of a Pennsylvania Subclass, defined as all Class members who purchased any Testosterone Booster in the Commonwealth of Pennsylvania.
- 258. Excluded from the Class and Subclasses are the officers, directors, and employees of any Defendant, any judicial officer presiding over this action, and the members of his or her immediate family and judicial staff.
- 259. Certification of the Class and Subclasses is sought pursuant to Rules 23(a), 23(b)(1), 23(b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure.
- 260. While Defendants have not made sales figures publicly available, the Class and Subclasses each have many thousands of members, and are so numerous that joinder of all members is impracticable.
- 261. There are numerous questions of fact and law common to the members of the Class and Subclasses which predominate over any questions affecting only individual members, including, without limitation: (a) whether Testofen has been clinically proven to increase free testosterone levels; (b) whether Defendants represented to Plaintiffs, the Class, and the Subclasses that Testofen has been clinically proven to increase free testosterone levels; (c) whether Defendants knew that these representations were false; (d) whether Defendants made these representations without a sufficient basis to believe that they were true; (e) whether Defendants expressly warranted that Testosterone Boosters had been clinically proven to increase free testosterone levels; (f) whether Testosterone Boosters fail to conform to such

express warranty, or the implied warranties of merchantability and fitness for a particular purpose; (g) whether Defendants' conduct violates Cal. Civ. Code § 1770(a)(2), (5), and/or (7); (h) whether Defendants' conduct constitutes fraudulent business acts or practices and/or deceptive, untrue, and misleading advertising in violation of the Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, et seq.; and (i) whether Defendants engaged in false advertising in violation of Cal. Bus. & Prof. Code § 17500, et seq.

- 262. Plaintiffs' claims are typical of the claims of the Class and Subclasses they represent, as Defendants' liability to each member of the Class and Subclasses is predicated on the same material misrepresentation.
- 263. Plaintiffs will fairly and adequately protect the interests of the Class and Subclasses, as they have no conflicts of interest with the other members of the Class or Subclasses, and have retained counsel experienced in complex consumer class actions.
- 264. The prosecution of separate actions by individual Class and Subclass members would create a risk of inconsistent or varying adjudications that would establish incompatible standards of conduct for Defendants.
- 265. Defendants have acted on grounds that apply generally to the Class and Subclasses, so that final injunctive and declaratory relief is appropriate respecting the Class and Subclasses as a whole.
- 266. A class action is superior to other available methods for fairly and efficiently adjudicating the controversy, in that the costs of litigation would likely exceed the potential recovery by individual Class and Subclass members, and there are no unusual difficulties in managing the litigation as a class action.

FIRST CLAIM FOR RELIEF VIOLATIONS OF RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1962(c)

(Against Gencor Defendants, GNC, and GNC Suppliers, on Behalf of the GNC Subclass)

- 267. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
- 268. Plaintiffs Garza, Aguero, Cowans, Erion, Ruhnke, Flores, Berger, Torres, and Baker bring this claim against Gencor Defendants, GNC, Direct Digital, Truderma, Force Factor, NAC, KingFisher, DreamBrands, PharmaFreak, NDS, MRI, and Naturade on behalf of the GNC Subclass.
- 269. At all relevant times, Defendants were employed by or associated with one or more enterprises engaged in, and the activities of which affect, interstate commerce.
- 270. Each enterprise is comprised of an association in fact of the Gencor Defendants, GNC, and GNC Suppliers, as follows:
 - a. Direct Digital, Gencor Defendants, and GNC
 - b. Truderma, Gencor Defendants, and GNC
 - c. NAC, Gencor Defendants, and GNC
 - d. Force Factor, Gencor Defendants, and GNC
 - e. KingFisher, Gencor Defendants, and GNC
 - f. DreamBrands, Gencor Defendants, and GNC
 - g. PharmaFreak, Gencor Defendants, and GNC
 - h. NDS, Gencor Defendants, and GNC
 - i. MRI, Gencor Defendants, and GNC
 - j. Prevention, LLC, NNC LLC, Gencor Defendants, and GNC
- 271. Defendants conducted and participated, directly or indirectly, in the operation and/or management of each of their respective enterprise's affairs through a pattern of racketeering activity consisting of numerous and repeated uses of the mails, commercial

interstate carriers, and interstate wire communications for the purpose of executing a scheme or artifice to defraud, all in violation of 18 U.S.C. § 1962(c).

- 272. The enterprises and their associates share a common purpose: to induce the members of the GNC Subclass into purchasing Testosterone Boosters based on the false representation that Testofen has been clinically proven to increase free testosterone levels.
- 273. The enterprises and their associates could not achieve their common purpose without one another's participation in their operation and/or management: the Gencor Defendants, to provide the GNC Suppliers with Testofen for inclusion in Testosterone Boosters; the GNC Suppliers, to formulate and provide GNC with Testosterone Boosters; and GNC, to market and sell Testosterone Boosters.
- 274. The enterprises had longevity sufficient to permit their associates to pursue and accomplish the enterprises' purpose: Testosterone Boosters are among GNC's best-selling products.
- 275. GNC provides the exclusive "launch" platform for a steady stream of new and "second generation" Testosterone Boosters, including Nugenix, Troxyphen, and High T products, giving GNC 100% of the revenue from the retail sales of these products.
- 276. As both GNC and the GNC Suppliers acknowledge, GNC uses its market dominance and influence with its customers to quickly drive sales of these products to levels far beyond what the GNC Suppliers could otherwise achieve.
- 277. The GNC Suppliers then introduce "new" and purportedly improved versions of each product, and GNC dubs each successive version as the "Newest Latest Greatest," creating an ever-growing product category, occupying ever-growing shelf space, and bringing ever-growing revenues and profits to GNC and its associates in the "Testofenterprise."
 - 278. As stated by GNC itself (at http://gnc.mediaroom.com/index.php?s=27086):

[W]e continue to maintain our market-leading position by providing our customers with the most comprehensive selection of cutting-edge products. And, we could not possibly provide the largest selection of products without building strong business

turns on the products in our stores.

279. A picture being worth 1,000 words, the symbiotic relationship between GNC, the Gencor Defendants, and the GNC Suppliers is illustrated most vividly by a photograph

(Exh. 113) which depicts the successive versions of each product line touted by GNC.

relationships with each of our vendors. Our vendors help us to

better . . . achieve our goals, and increase the sales and inventory

- 280. In a typical turn of a "Testofenterprise" fraudulent marketing cycle, on May 9, 2014, GNC sent out a mass email (Exh. 114) touting "FORCE FACTOR THE ULTIMATE PERFORMANCE STACK," which includes a bottle of Test X180, as its "DEAL OF THE DAY." Clicking on the link to "SHOP NOW" takes recipients of the email to GNC's website (Exh. 115) to purchase Stack Factor 2 With Test X180, where GNC states unequivocally that "When you work out, the Testofen in Test X180 raises your free testosterone levels."
- 281. The packaging for Stack Factor 2 With Test X180 (Exh. 116), displayed on GNC's website as well as in its retail stores, states that "The main ingredient, Testofen, is the only natural compound that has been clinically demonstrated to increase free testosterone levels"
- 282. On GNC's website, clicking on the "Health Notes" tab on the product page for Stack Factor 2 With Test X180 (Exh. 117) brings up a list of 54 ingredients and their supposed health benefits. Conspicuously absent from this list is any mention of Testofen. GNC has *omitted* its ineffective and insufficient "disclosure," buried three levels deep on its product page for Test X180 (*see* para. 207, *supra*), that "A number of supplements are marketed as natural testosterone support, though these effects have not been demonstrated in clinical research."
- 283. On May 15, 2014, GNC sent out a mass email (Exh. 118) touting "truDERMA TROXYPHEN or TROXYPHEN ELITE," which it describes as "the advanced formula," as its "DEAL OF THE DAY." Clicking on the link to "SHOP NOW" takes recipients of the email to GNC's website to purchase Troxyphen or Troxyphen Elite, which GNC identifies as a "NEW" product. While GNC's website continues to state that Troxyphen contains

21

22

23 24

26 27

25

28

"Ingredients Shown to Help Raise Testosterone" and "naturally and significantly increase[es] your base line Testosterone levels" (Exh. 70), GNC has now removed its ineffective and insufficient "disclosure," formerly buried three levels deep on its product page for Troxyphen (see para. 207, supra), that "A number of supplements are marketed as natural testosterone support, though these effects have not been demonstrated in clinical research."

- Defendants, having devised a scheme or artifice to defraud, transmitted or 284. caused to be transmitted by means of wire, radio, and television communication in interstate commerce, the material misrepresentations set forth above, for the purpose of executing such scheme or artifice to defraud, in violation of 18 U.S.C. § 1343.
- 285. Defendants, having devised a scheme or artifice to defraud, for the purpose of executing such scheme or artifice, deposited or caused to be deposited in the mail and with commercial interstate carriers, including United Parcel Service and Federal Express, matters and things to be sent or delivered by the Postal Service, United Parcel Service, Federal Express, and DHL, including, without limitation, the Testosterone Boosters marketed and sold by Defendants on the websites identified above, in violation of 18 U.S.C. § 1341.
- As a direct and proximate result of Defendants' racketeering activities and 286. violations of 18 U.S.C. § 1962(c), Plaintiffs have been injured in their business and property in that they purchased Testosterone Boosters based on the material and false representation that these products have been clinically proven to increase free testosterone levels.
- 287. Pursuant to 18 U.S.C. § 1964(c), Plaintiffs and members of the GNC Subclass seek actual damages, equal to the amounts paid by Plaintiffs Garza, Aguero, Cowans, Erion, Ruhnke, Flores, Berger, Torres, and Baker, and the members of the GNC Subclass, for any Testosterone Booster purchased from GNC or any of its franchisees, treble damages, and attorneys' fees and costs.

SECOND CLAIM FOR RELIEF VIOLATIONS OF CONSUMER LEGAL REMEDIES ACT

(Against All Defendants)

- 288. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
- 289. Plaintiffs and the other members of the Class are "consumers" as defined in Cal. Civ. Code § 1761(d).
- 290. The Testosterone Boosters purchased by Plaintiffs and the other members of the Class are "goods" as defined in Cal. Civ. Code § 1761(a).
- 291. Defendants' representations, set forth above, that Testosterone Boosters have been clinically proven to increase free testosterone levels are false, in violation of § 1770(a)(2), which proscribes "[m]isrepresenting the . . . approval, or certification of goods"
- 292. Defendants' representations, set forth above, that Testosterone Boosters have been clinically proven to increase free testosterone levels are false, in violation of § 1770(a)(5), which proscribes "[r]epresenting that goods . . . have . . . approval, characteristics, ingredients, uses, [or] benefits . . . which they do not have"
- 293. Defendants' representations, set forth above, that Testosterone Boosters have been clinically proven to increase free testosterone levels are false, in violation of § 1770(a)(7), which proscribes "[r]epresenting that goods or services are of a particular standard, quality, or grade, . . . if they are of another."
- 294. Pursuant to Cal. Civ. Code § 1780(a)(2), Plaintiffs seek an order enjoining Defendants from the violations of Cal. Civ. Code § 1770(a)(2), (5), and (7) alleged herein.
- 295. On April 18, 2013, the Gencor Defendants, Direct Digital, and GNC were served by certified mail, return receipt requested, at their principal places of business with the notice required by Cal. Civ. Code § 1782(a), sent on behalf of purchasers of Nugenix, demanding that they provide within 30 days "sufficient information to validate your claim" that Testofen has been clinically proven to increase free testosterone levels, or face litigation

seeking "the recovery of all amounts paid by consumers for Nugenix." Neither the Gencor Defendants, Direct Digital, nor GNC responded to the notice within 30 days after its receipt.

- 296. On May 15, 2014, Truderma was served by certified mail, return receipt requested, at its principal place of business with the notice required by Cal. Civ. Code § 1782(a), demanding that it cease the violations alleged herein, and restore to the members of the Troxyphen Subclass all amounts paid for Troxyphen and Troxyphen Elite. Truderma did not respond to or comply with the demands made in the notice within 30 days after its receipt.
- 297. On May 15, 2014, Force Factor was served by certified mail, return receipt requested, at its principal place of business with the notice required by Cal. Civ. Code § 1782(a), demanding that it cease the violations alleged herein, and restore to the members of the Test X180 Subclass all amounts paid for Test X180, Test X180 Alpha, and Test X180 Ignite. Force Factor did not respond to or comply with the demands made in the notice within 30 days after its receipt.
- 298. On June 17, 2014, NAC was served by certified mail, return receipt requested, at its principal place of business with the notice required by Cal. Civ. Code § 1782(a), demanding that it cease the violations alleged herein, and restore to the members of the Class all amounts paid for Ageless Male containing Testofen. NAC did not respond to or comply with the demands made in the notice within 30 days after its receipt.
- 299. On May 15, 2014, KingFisher was served by certified mail, return receipt requested, at its principal place of business with the notice required by Cal. Civ. Code § 1782(a), demanding that it cease the violations alleged herein, and restore to the members of the Class all amounts paid for High T, High T Senior, High T Black, and High T Caffeine Free. KingFisher did not respond to or comply with the demands made in the notice within 30 days after its receipt.
- 300. On May 15, 2014, DreamBrands was served by certified mail, return receipt requested, at its principal place of business with the notice required by Cal. Civ. Code §

1782(a), demanding that it cease the violations alleged herein, and restore to the members of the Class all amounts paid for Mdrive and Mdrive Elite. DreamBrands did not respond to or comply with the demands made in the notice within 30 days after its receipt.

- 301. On May 15, 2014, PharmaFreak was served by certified mail, return receipt requested, at its principal place of business with the notice required by Cal. Civ. Code § 1782(a), demanding that it cease the violations alleged herein, and restore to the members of the Class all amounts paid for Test Freak. PharmaFreak did not respond to or comply with the demands made in the notice within 30 days after its receipt.
- 302. On May 15, 2014, NDS was served by certified mail, return receipt requested, at its principal place of business with the notice required by Cal. Civ. Code § 1782(a), demanding that it cease the violations alleged herein, and restore to the members of the Class all amounts paid for PMD N-TEST 600 and PMD Flex Stack. NDS did not respond to or comply with the demands made in the notice within 30 days after its receipt.
- 303. On May 15, 2014, MRI was served by certified mail, return receipt requested, at its principal place of business with the notice required by Cal. Civ. Code § 1782(a), demanding that it cease the violations alleged herein, and restore to the members of the Class all amounts paid for NO2 Red Test. MRI did not respond to or comply with the demands made in the notice within 30 days after its receipt.
- 304. On May 15, 2014, Prevention LLC and NNC LLC were served by certified mail, return receipt requested, at its principal place of business with the notice required by Cal. Civ. Code § 1782(a), demanding that they cease the violations alleged herein, and restore to the members of the Class all amounts paid for Ultra T Gold, Vitali-T-Aid, and Vitali-T-Aid Energy. Prevention LLC and NNC LLC did not respond to or comply with the demands made in the notice within 30 days after its receipt.
- 305. On May 15, 2014, Premium Nutraceuticals was served by certified mail, return receipt requested, at its principal place of business with the notice required by Cal. Civ. Code §

1782(a), demanding that it cease the violations alleged herein, and restore to the members of the Class all amounts paid for Testoril. Premium Nutraceuticals did not respond to or comply with the demands made in the notice within 30 days after its receipt.

- 306. Pursuant to Cal. Civ. Code § 1780(a)(1) and (3), Plaintiffs seek actual damages and restitution: (a) against the Gencor Defendants, equal to the amounts paid by the members of the Class for any Testosterone Booster; (b) against GNC, equal to the amounts paid by the members of the GNC Subclass for any Testosterone Booster purchased from GNC or any of its franchisees; and (c) against each of the Manufacturer Defendants, equal to the amounts paid for any Testosterone Booster by the members of the corresponding subclass (*see* paras. 245-255, *supra*).
- 307. Pursuant to Cal. Civ. Code § 1780(a)(4), Plaintiffs seek punitive damages against Defendants for representing that Testosterone Boosters are clinically proven to increase free testosterone levels, with knowledge of the falsity of those representations.
- 308. The affidavit required by Cal. Civ. Code § 1780(d) is attached hereto as Exhibit 119.

THIRD CLAIM FOR RELIEF VIOLATIONS OF UNFAIR COMPETITION LAW

- 309. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
- 310. Defendants' false representations that Testosterone Boosters have been clinically proven to increase free testosterone levels constitute fraudulent business acts or practices and deceptive, untrue, and misleading advertising in violation of the Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, et seq.
- 311. Defendants' representations would have been material to a reasonable person in deciding whether or not to purchase a Testosterone Booster.

- 312. Plaintiffs and the Class justifiably relied upon Defendants' representations in purchasing Testosterone Boosters.
- 313. Defendants' violations of Cal. Civ. Code § 1770(a)(2), (5), and (7) alleged herein constitute unlawful business practices in violation of the Unfair Competition Law.
- 314. As a result of Defendants' violations, Plaintiffs and the members of the Class have suffered injury in fact and lost money.
- 315. Pursuant to Cal. Bus. & Prof. Code § 17203, Plaintiffs seek an order enjoining these violations, and restoring to Plaintiffs and members of the Class all amounts acquired by Defendants as a result of these violations.

FOURTH CLAIM FOR RELIEF VIOLATIONS OF FALSE ADVERTISING LAW

- 316. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
- 317. Defendants' representations that Testosterone Boosters have been clinically proven to increase free testosterone levels are false.
- 318. Defendants know, or in the exercise of reasonable care should know, that these representations are false.
- 319. Defendants made these representations with the intent to induce Plaintiffs and the members of the Class to purchase Testosterone Boosters.
- 320. Defendants' false representations induced Plaintiffs and the members of the Class to purchase Testosterone Boosters.
- 321. Defendants made or disseminated these representations, or caused them to be made or disseminated, before the public in the State of California, in the manner set forth above, including by television, radio, and over the internet, in violation of the False Advertising Law, Cal. Bus. & Prof. Code § 17500, et seq.

- 322. The Gencor Defendants made or disseminated these representations, or caused them to be made or disseminated, from the State of California before the public nationally, in violation of Cal. Bus. & Prof. Code § 17500, *et seq*.
- 323. Defendants' representations that Testosterone Boosters have been clinically proven to increase free testosterone levels violate the express terms of Cal. Bus. & Prof. Code § 17508, which makes it "unlawful for any person doing business in California and advertising to consumers in California to make any false or misleading advertising claim, including claims that (1) purport to be based on factual, objective, or clinical evidence"
- 324. As a result of these violations, Plaintiffs and the members of the Class have suffered injury in fact and lost money.
- 325. Pursuant to Cal. Bus. & Prof. Code § 17535, Plaintiffs seek an order enjoining these violations, and restoring to Plaintiffs and members of the Class all amounts acquired by Defendants as a result of these violations.

FIFTH CLAIM FOR RELIEF BREACH OF EXPRESS WARRANTY

- 326. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
 - 327. Testosterone Boosters are goods.
 - 328. Plaintiffs and the other members of the Class purchased Testosterone Boosters.
- 329. Defendants' representations that Testosterone Boosters were clinically proven to increase free testosterone levels constituted an express warranty that Testosterone Boosters conformed to that affirmation or promise.
- 330. Defendants' descriptions of Testosterone Boosters as having been clinically proven to increase free testosterone levels constituted an express warranty that Testosterone Boosters conformed to that description.

- 331. The Testosterone Boosters purchased by Plaintiffs and the Class were not, in fact, clinically proven to increase free testosterone levels, in breach of these express warranties.
- 332. As a direct and proximate result, Plaintiffs and the Class have sustained damages equal to the amounts paid for Testosterone Boosters.

SIXTH CLAIM FOR RELIEF BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(Against All Defendants)

- 333. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
 - 334. Testosterone Boosters are goods.
 - 335. Plaintiffs and the other members of the Class purchased Testosterone Boosters.
- 336. At all times relevant herein, Defendants were in the business of selling Testofen or Testosterone Boosters containing Testofen.
- 337. The implied warranty or merchantability, implied in every contract for the sale of goods, includes the requirement that the goods conform to the promises or affirmations of fact made on the container or label.
- 338. Testosterone Boosters do not conform to the promises or affirmations of fact made on the container or label, set forth above, that they are clinically proven to increase free testosterone levels, in breach of the implied warranty of merchantability.
- 339. As a direct and proximate result, Plaintiffs and the Class have sustained damages equal to the amounts paid for Testosterone Boosters.

SEVENTH CLAIM FOR RELIEF BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

- 340. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
 - 341. Testosterone Boosters are goods.

- 342. Plaintiffs and the other members of the Class purchased Testosterone Boosters for the purpose of increasing their free testosterone levels.
- 343. At the time of purchase, Defendants knew or had reason to know that Plaintiffs and the other members of the Class intended to use Testosterone Boosters for the purpose of increasing their free testosterone levels.
- 344. At the time of purchase, the Gencor Defendants and the Manufacturer Defendants knew or had reason to know that Plaintiffs and the other members of the Class were relying on their skill and judgment as manufacturers of nutritional supplements in formulating Testosterone Boosters.
- 345. Plaintiffs and the Class justifiably relied on Defendants' skill and judgment as manufacturers of nutritional supplements in formulating Testosterone Boosters.
- 346. At the time of purchase, GNC knew or had reason to know that Plaintiffs Garza, Aguero, Cowans, Erion, Ruhnke, Flores, Berger, Torres, and Baker, and the other members of the GNC Subclass were relying on GNC's skill and judgment in the selection of Testosterone Boosters.
- 347. Testosterone Boosters are not clinically proven to increase free testosterone levels, in breach of the implied warranty of fitness for a particular purpose.
- 348. As a direct and proximate result, Plaintiffs and the Class have sustained damages equal to the amounts paid for Testosterone Boosters.

EIGHTH CLAIM FOR RELIEF FRAUD

- 349. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
- 350. Defendants' representations that Testosterone Boosters have been clinically proven to increase free testosterone levels, set forth above, are representations of fact.

- 351. Defendants' representations that Testosterone Boosters have been clinically proven to increase free testosterone levels, set forth above, were false when made.
- 352. These representations would have been material to a reasonable person in deciding whether or not to purchase a Testosterone Booster.
- 353. Defendants knew that these representations were false at the time they were made, or acted with reckless disregard as to their truth or falsity.
- 354. Defendants made these representations with the intent to induce Plaintiffs and the Class to purchase Testosterone Boosters.
- 355. Plaintiffs and the Class justifiably relied upon Defendants' misrepresentations by purchasing Testosterone Boosters.
- 356. As a direct and proximate result, Plaintiffs and the Class have suffered damages equal to the amounts paid for Testosterone Boosters.
- 357. To punish and deter their ongoing fraud, Defendants are also liable for punitive or exemplary damages.

NINTH CLAIM FOR RELIEF NEGLIGENT MISPREPRESENTATION

- 358. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
- 359. Defendants' representations that Testosterone Boosters have been clinically proven to increase free testosterone levels, set forth above, are representations of fact.
- 360. Defendants' representations that Testosterone Boosters have been clinically proven to increase free testosterone levels, set forth above, were false when made.
- 361. These representations would have been material to a reasonable person in deciding whether or not to purchase a Testosterone Booster.
- 362. Defendants made these representations without reasonable grounds for believing them to be true.

- 363. Defendants made these representations with the intent to induce Plaintiffs and the Class to purchase Testosterone Boosters.
- 364. Plaintiffs and the Class justifiably relied upon Defendants' misrepresentations by purchasing Testosterone Boosters.
- 365. As a direct and proximate result, Plaintiffs and the Class have suffered damages equal to the amounts paid for Testosterone Boosters.

TENTH CLAIM FOR RELIEF RESTITUTION

(Against All Defendants)

- 366. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
- 367. Defendants have received a benefit from Plaintiffs and the Class, who have purchased Testosterone Boosters, profiting Defendants.
- 368. Defendants received these benefits from Plaintiffs and the Class by selling Testosterone Boosters under false pretenses, as set forth above.
- 369. It would be unjust and inequitable to permit Defendants to retain the benefits received from Plaintiffs and the Class.
 - 370. Plaintiffs seek restitution of all such benefits, according to proof.

ELEVENTH CLAIM FOR RELIEF VIOLATIONS OF PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW

(Against Gencor Defendants, GNC, Direct Digital, NAC, and KingFisher, on Behalf of the Pennsylvania Subclass)

- 371. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.
- 372. Should the Court determine that the Second, Third and/or Fourth Claims for Relief alleged herein are unavailable to Class members whose purchases of Testosterone Boosters were made outside the State of California, Plaintiff Baker asserts this claim, in the

alternative, against the Gencor Defendants, GNC, Direct Digital, NAC, and KingFisher on behalf of the Pennsylvania Subclass.

- 373. The Testosterone Boosters purchased by Plaintiff Baker and the other members of the Pennsylvania Subclass are "goods" as defined in 73 P.S. § 201-9.2(a).
- 374. The Testosterone Boosters purchased by Plaintiff Baker and the other members of the Pennsylvania Subclass were purchased for "personal purposes" as defined in 73 P.S. § 201-9.2(a).
- 375. Defendants' representations, set forth above, that Testosterone Boosters have been clinically proven to increase free testosterone levels are false, and constitute unfair competition and deceptive acts or practices as defined by 73 P.S. § 201-2(4)(ii), which proscribes "[c]ausing likelihood of confusion or of misunderstanding as to the . . . approval, or certification of goods"
- 376. Defendants' representations, set forth above, that Testosterone Boosters have been clinically proven to increase free testosterone levels are false, and constitute unfair competition and deceptive acts or practices as defined by 73 P.S. § 201-2(4)(v), which proscribes "[r]epresenting that goods . . . have . . . approval, characteristics, ingredients, uses, [or] benefits . . . that they do not have"
- 377. Defendants' representations, set forth above, that Testosterone Boosters have been clinically proven to increase free testosterone levels are false, and constitute unfair competition and deceptive acts or practices as defined by 73 P.S. § 201-2(4)(vii), which proscribes "[r]epresenting that goods or services are of a particular standard, quality, or grade, . . . if they are of another."
- 378. Defendants' representations, set forth above, that Testosterone Boosters have been clinically proven to increase free testosterone levels are false, and constitute unfair competition and deceptive acts or practices as defined by 73 P.S. § 201-2(4)(xiv), which

proscribes "[f]ailing to comply with the terms of any written guarantee or warranty given to the buyer at, prior to or after a contract for the purchase of goods or services is made."

- 379. Defendants' representations, set forth above, that Testosterone Boosters have been clinically proven to increase free testosterone levels are false, and constitute unfair competition and deceptive acts or practices as defined by 73 P.S. § 201-2(4)(xxi), which proscribes "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding."
- 380. The unfair methods of competition and deceptive acts or practices enumerated above are unlawful in violation of 73 P.S. § 201-3.
- 381. Plaintiff Baker and the other members of the Pennsylvania Subclass purchased Testosterone Boosters in reliance on Defendants' false representations that Testosterone Boosters have been clinically proven to increase free testosterone levels.
- 382. Plaintiff Baker and the other members of the Pennsylvania Subclass have suffered ascertainable losses of money as a result of the unfair methods of competition and deceptive acts or practices enumerated above.
- 383. Pursuant to 73 P.S. § 201-9.2(a), Plaintiff Baker and the other members of the Pennsylvania Subclass seek actual damages equal to the amounts paid by them for any Testosterone Booster purchased in the Commonwealth of Pennsylvania, treble damages, reasonable attorneys' fees, costs, and such additional relief as the Court deems necessary or proper.

TWELFTH CLAIM FOR RELIEF VIOLATIONS OF ARIZONA CONSUMER FRAUD ACT

(Against Gencor Defendants, GNC, Truderma, and KingFisher on Behalf of the Arizona Subclass)

384. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.

- 385. Should the Court determine that the Second, Third and/or Fourth Claims for Relief alleged herein are unavailable to Class members whose purchases of Testosterone Boosters were made outside the State of California, Plaintiff Torres asserts this claim, in the alternative, against Gencor Defendants, GNC, Truderma, and KingFisher on behalf of the Arizona Subclass.
- 386. Defendants' representations, set forth above, that Testosterone Boosters have been clinically proven to increase free testosterone levels constitute "advertisements" as defined in A.R.S. § 44-1521(1).
- 387. The Testosterone Boosters purchased by Plaintiff Torres and the other members of the Arizona Subclass are "merchandise" as defined in A.R.S. § 44-1521(5).
- 388. The purchase of Testosterone Boosters by Plaintiff Torres and the other members of the Arizona Subclass constitute "sales" as defined in A.R.S. § 44-1521(7).
- 389. Defendants' representations, set forth above, that Testosterone Boosters have been clinically proven to increase free testosterone levels are false, and constitute unlawful practices as defined by A.R.S. § 44-1522(A), which proscribes "[t]he act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact . . . in connection with the sale or advertisement of any merchandise"
- 390. Defendants made these false representations with the intent that others rely on them.
- 391. In purchasing Testosterone Boosters, Plaintiff Torres and the other members of the Arizona Subclass relied on Defendants' misrepresentations.
- 392. As a result of Defendants' violations of A.R.S. § 44-1522(A), Torres and the other members of the Arizona Subclass have suffered damages, and seek actual damages equal to the amounts paid by them for any Testosterone Booster purchased in the State of Arizona, punitive damages, reasonable attorneys' fees, and costs.

1	PRAYER FOR RELIEF			
2	WHE	WHEREFORE, Plaintiffs pray for relief as follows:		
3	1.	For an order enjoinin	g Defendants from continuing the fraudulent business	
4		practices and false ad	lvertising alleged herein;	
5	2.	For an order restoring	g to Plaintiffs and the members of the Class the amounts	
6		wrongfully acquired from them by Defendants;		
7	3.	For compensatory damages, according to proof;		
8	4.	For actual damages, according to proof;		
9	5.	5. For an order, pursuant to Cal. Civ. Code § 2224, imposing a constructive trust		
10	upon the assets of Defendants acquired by means of the wrongful acts alleged			
11	6.	6. For punitive or exemplary damages;		
12	7.	For attorney's fees an	nd costs, as allowed by statute and Cal. Govt. Code §	
13		1021.5; and		
14	8.	For such other and fu	orther relief as the Court deems just and proper.	
15				
16	DEMAND FOR JURY TRIAL Plaintiffs demand a trial by jury on all claims so triable.			
17				
18				
19			Respectfully submitted,	
20				
21	Dated: December 31, 2014		<u>Is Barry Himmelstein</u> Barry Himmelstein (SBN 157736)	
22			barry@himmellaw.com HIMMELSTEIN LAW NETWORK	
23			2000 Powell St., Suite 1605 Emeryville, CA 94608-1861	
24			Telephone: (510) 450-0782 Facsimile: (510) 924-0403	
25			Attorney for Plaintiffs	
26				
27				
28				
			0.0	