#### IN THE CIRCUIT COURT OF COLE COUNTY, MISSOURI

TOMMY ROBBINS, DANIEL CAMEY, RAYMOND ALVANDI and GERARD BUTLER, Individually and on behalf of all others similarly situated.

Civil Action No. 16AC-CC00366

The Hon. Jon E. Beetem

Plaintiffs,

v.

GENCOR NUTRIENTS, INC., GENCOR PACIFIC, INC., GE NUTRIENTS, INC., DIRECT DIGITAL, LLC, PHARMAFREAK HOLDINGS, INC., FORCE FACTOR, LLC, DREAMBRANDS, INC., GENERAL NUTRITION CENTERS, INC., GENERAL NUTRITION CORPORATION, GNC CORPORATION, S&G PROPERTIES, LLC, KING FISHER MEDIA, LLC, and PREVENTION, LLC d/b/a NATURADE,

Defendants.

# AMENDED CLASS ACTION PETITION AND JURY DEMAND

Plaintiffs Tommy Robbins, Daniel Camey, Raymond Alvandi, and Gerard Butler ("Plaintiffs"), on behalf of themselves and all others similarly situated ("Class Members" or the "Class"), allege against Defendants Gencor Nutrients, Inc., Gencor Pacific, Inc., and GE Nutrients, Inc. (collectively, "Gencor"), Direct Digital, LLC ("Direct Digital"), PharmaFreak Holdings, Inc. ("Pharmafreak"), Force Factor, LLC ("Force Factor"), Dreambrands, Inc. ("Dreambrands"), KingFisher Media, LLC ("Kingfisher"), Prevention LLC d/b/a Naturade ("Naturade"), General Nutrition Centers, Inc., General Nutrition Corporation, GNC Corporation, and S&G Properties, LLC (collectively, the "Defendants"), the following facts and claims upon personal knowledge, investigation of counsel, and information and belief:

#### NATURE OF THE CASE

- 1. This case arises out of Defendants' deceptive and misleading marketing and sale of Testofen and/or supplements containing Testofen—a proprietary botanical ingredient designed to boost testosterone levels (the "Testofen Products").
- 2. Defendants market the Testofen Products<sup>1</sup> as "groundbreaking" supplements designed to dramatically boost testosterone levels by as much as 99%. As a result of this purported boost in testosterone, users of Testofen Products will experience a variety of benefits, including improved orgasms, improved cognition, the promotion of fat loss, heightened libido, enhanced sexual performance, strengthened blood flow, promote or build muscle mass, improved power and/or stamina.
- 3. Furthermore, Defendants claim that Testofen Products are that these claims were backed by clinical studies and/or research. By claiming that Testofen has undergone clinical studies, Defendants are representing to consumers that credible scientific evidence supports Defendants' statements that the Product increases, boosts, and/or supports "free" testosterone levels.
- 4. Defendants' representations, however, were materially false, misleading and deceptive when made. The Testofen Products and the proprietary blend of ingredients contained therein (including Testofen) do not significantly boost free testosterone levels in men. Nor do Testofen Products increase lean muscle mass, burn fat, or boost one's sex drive or libido.

Gold, Vitali-T-Aid, Vitali-T-Aid Energy, and Testoril.

<sup>&</sup>lt;sup>1</sup> The "Testofen Product" means all products containing Testofen, manufactured, supplied, marketed, sold and/or distributed by Defendants for personal or household use and not for resale, including, but not limited to: 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, PMD Platinum Test 600, AMP Test 1700, NO2 Red Test, Ultra T

- 5. Defendants materially misled thousands of consumers, including a significant number of men who are prone to normally decreasing testosterone levels, through a massive advertising campaign. Defendants' advertising involves numerous materially false and misleading statements concerning the Testofen Products, which have injured Plaintiffs and the Class by inducing them to purchase the Product at a substantial price premium. As a result, Defendants should be held liable for their deceptive conduct in the sale and marketing of Testofen Products.
- 6. As such, Defendants have engaged in false, deceptive, and misleading marketing and advertising practices in violation of the Missouri Merchandising Practices Act, Rev. Stat. Mo. §§ 407.010, et seq. ("MMPA"); Breach of Express Warranty; Breach of Implied Warranty of Merchantability; for disgorgement of Defendants' unjust enrichment; California's Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, et seq.; California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, et seq.; and California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, et seq.

#### **PARTIES**

- 7. Plaintiff Tommy Robbins is a resident of Phelps County, Missouri. On at least one occasion during the Class Period (as defined below), Plaintiff Robbins purchased products containing Testofen at a General Nutrition Center ("GNC") store, located in Jefferson City, Missouri, for personal, family, or household purposes. Specifically, Plaintiff Robbins purchased the products "AMP Test 1700" for \$99.99 and "Platinum Test 600" for \$79.99, inclusive of GNC member price discounts. Plaintiff Robbins's claim is typical of Class Members in this regard.
- 8. Plaintiff Daniel Camey is a citizen of the State of California. On at least one occasion during the Class Period, Plaintiff Camey purchased products containing Testofen at a

GNC store located on Philadelphia Street, in Chino, California, for personal, family, or household purposes. Specifically, Plaintiff Camey purchased "Test X180" products for approximately \$60.00 to \$70.00. Plaintiff Camey's claim is typical of Class Members in this regard.

- 9. Plaintiff Raymond Alvandi is a citizen of the State of California. During the Class Period, Plaintiff Alvandi purchased products containing Testofen manufactured, marketed, or sold by Defendants described and at issue in this Complaint for personal, family, or household purposes. Specifically, Plaintiff Alvandi purchased one Test X180 Ignite in or around January of 2014 from a GNC store near his home in Los Angeles, California, for approximately \$79.95. Plaintiff Alvandi's claim is typical of Class Members in this regard.
- 10. Plaintiff Gerard Butler is a citizen of the State of California. On at least one occasion during the Class Period, Plaintiff Butler purchased products containing Testofen at a GNC store located in Los Angeles, California, for personal, family, or household purposes. Specifically, Plaintiff Butler purchased "Nugenix" products for approximately \$70.00. Plaintiff Butler also paid for shipping of a trial offer during the Class Period. Plaintiff Butler's claims are typical of Class Members in this regard.
- 11. Defendant Gencor Nutrients, Inc. was founded in or about 2001 and is a California corporation having its principal place of business in Orange County, California. On information and belief, Gencor Nutrients, Inc. also operates or previously operated under the name Gencor Pacific, Inc.
- 12. Defendant Gencor Pacific, Inc. is a Texas corporation with a registered office street address in Austin, Texas.

- 13. Defendant GE Nutrients, Inc. is a California corporation with its principal place of business in Orange County, California.
- 14. Collectively, Defendants Gencor Nutrients, Inc., Gencor Pacific, Inc., and GE Nutrients are referred to herein as "Gencor" or the "Gencor Defendants."
- 15. The Gencor Defendants continuously and systematically conduct business in Missouri and/or regularly do and or solicit business or derive substantial revenues from product services, or products used or consumed in Missouri. For example, Gencor supplies the Brand Defendants with supplies of the Testofen ingredient. Gencor touts itself as a research-based group providing "science-driven" ingredients that are designed to improve quality of life for consumers in a broad range of life stages, which are purportedly validated with human clinical trials and safety studies. Gencor manufactures, markets, and sells specialized ingredients, including Testofen, in over 50 countries worldwide. The Gencor Defendants took an active role in marketing the Products and/or aided and abetted the unlawful practices of Brand Defendants by, among other acts: providing Brand Defendants and the public with purported "clinical studies" that supposedly show the efficacy of the Testofen ingredient. Furthermore, the Gencor Defendants provided Brand Defendants with a list of "Approved Health Claims" for the ingredient, including the claims that Testofen: "[s]upports healthy levels of free testosterone; [p]romotes sexual desire and vitality; [r]educes recovery time following sexual activity; [s]upports muscle mass; and [p]romotes healthy energy levels."<sup>2</sup> Further, the Gencor Defendants engaged in "indirect deception" by intending or having reason to expect that the above misleading claims would be repeated and/or its substance communicated to proposed Class Members, and that it would influence their conduct in the purchase of products containing Testofen. Moreover, in creating the Testofen ingredient and providing Brand Defendants with

<sup>&</sup>lt;sup>2</sup> http://www.gencorpacific.com/index.php/featured-ingredients/testofen (last visited April 10, 2018).

the "Approved Health Claims" and purported "clinical studies," the Gencor Defendants furnished the means by which the ultimate fraud was accomplished and are therefore equally liable.

- 16. Defendant Direct Digital, LLC is a Delaware limited liability company that maintains a principal place of business at 364 Boylston Street in Boston, Massachusetts. Direct Digital creates, advertises, and sells a wide variety of supplements, including Instaflex Joint Support, Instaflex Bone Support, Instaflex Multivitamin, Instaflex Muscle Support, Nugenix Testosterone Booster, Nugenix Prostate Support, and Nugenix DHEA. At all times relevant to this Complaint, acting individually or in concert with others, Direct Digital LLC marketed and sold Nugenix to consumers in Missouri and throughout the United States.
- 17. Defendant PharmaFreak Holdings, Inc. ("PharmaFreak") is a Canadian corporation with its principal place of business located at 2900 550 Burrard Street, Vancouver BC V6C 0A3, Canada. PharmaFreak creates, advertises, and sells a wide variety of supplements, including Test Freak, which PharmaFreak claims is a "hybrid vitamin/mineral supplement made up of clinically-researched ingredients." At all times relevant to this Complaint, acting individually or in concert with others, PharmaFreak marketed and sold Test Freak to consumers in Missouri and throughout the United States.
- 18. Defendant Force Factor, LLC is a Delaware limited liability company that maintains its principal place of business at 24 School Street, Suite 401, in Boston, Massachusetts. Force Factor creates, advertises, and sells a wide variety of supplements, including Factor 2, BRX, Ramp UP, Glutamine, Ketabolic Pro, Omega 3, Test X180, Test X180 Alpha, and Test X180 Ignite. Defendant Force Factor represents that the Company's "skyrocketing success is a testament to the quality and effectiveness of [its] supplements." At all times relevant to this

Complaint, acting individually or in concert with others, Force Factor marketed and sold Testofen Products to consumers in Missouri and throughout the United States.

- 19. Defendant Dreambrands, Inc. is an Arizona corporation with its principal place of business in Phoenix, Arizona. Dreambrands creates, advertises, and sells a wide variety of supplements, including Mdrive and Mdrive Elite. Dreambrands represents that "[i]n an industry overrun by mass manufacturers who slap labels on generic formulas and pay doctors to stand behind claims, [Dreambrands is] a small but mighty research company founded by lifetime formulators, chemists, scientists and health advocates." At all times relevant to this Complaint, acting individually or in concert with others, Dreambrands, Inc. marketed and sold Mdrive and Mdrive Elite to consumers in Missouri and throughout the United States.
- 20. Defendant KingFisher Media, LLC ("KingFisher"), is a Delaware limited liability company that maintains its principal place of business located at 317 W 6160 S Murray, Utah 84107. KingFisher creates, advertises, and sells a wide variety of supplements, including its High T line of products, which KingFisher claims are "BACKED BY SCIENCE [High T] Turbo T Testosterone is supported by proven science to promote healthy testosterone levels. [High T] Turbo T Testosterone is a top Fenugreek Testosterone Booster on Amazon, because it's backed by 100% science-based ingredients that have been shown to boost your testosterone levels with regular use." At all times relevant to this Complaint, acting individually or in concert with others, KingFisher marketed and sold its High T products to consumers in Missouri and throughout the United States.
- 21. Defendant Prevention LLC d/b/a Naturade is a Delaware limited liability company that maintains a principal place of business at 2030 Main Street, Suite 630, in Irvine, California. Naturade represents itself as a "leader in the manufacture of the most efficacious

<sup>&</sup>lt;sup>3</sup> http://www.dreambrands.com/about (last visited Mar. 15, 2018).

products in the nutrition and supplements sector for decades" that sells its products in "leading retailers across the natural and mass retail channels." At all times relevant to this Complaint, acting individually or in concert with others, Prevention LLC marketed and sold its Ageless Ultra T Gold, Vitali-T-Aid, and Vitali-T-Aid Energy products to consumers in Missouri and throughout the United States.

- 22. Collectively, Defendants Direct Digital, PharmaFreak, Force Factor, Dreambrands, KingFisher, and Naturade (defined below) are referred to herein as the "Brand Defendants."
- 23. Defendant General Nutrition Centers, Inc., is a Pennsylvania corporation with its principal place of business in Pittsburgh, Pennsylvania.
- 24. Defendant General Nutrition Corporation is a Pennsylvania corporation with its principal place of business in Pittsburgh, Pennsylvania. General Nutrition Corporation is registered to do business in Missouri under charter number F00555739.
- 25. Defendant GNC Corporation is a Delaware corporation with its principal place of business in Pittsburgh, Pennsylvania.
- 26. Defendant S&G Properties, LLC is a Pennsylvania limited liability company having its principal place of business in Harleysville, Pennsylvania.
- 27. Collectively, Defendants General Nutrition Centers, Inc., General Nutrition Corporation, GNC Corporation, and S&G Properties, LLC are referred to herein as "GNC" or the "GNC Defendants."
- 28. The GNC Defendants are one of the country's largest multi-channel specialty retailers of dietary and nutritional supplements, operating more than 6,500 retail locations

throughout the United States including Missouri, and specialize in the sale of and advice to consumers about nutritional supplements. In fact, the GNC Defendants tout that:

GNC sets the standard in the nutritional supplement industry by demanding truth in labeling, ingredient safety and product potency, all while remaining on the cutting-edge of nutritional science. As our company has grown over the years, so has our commitment to Living Well. In fact, GNC is the world's largest company of its kind devoted exclusively to helping its customers improve the quality of their lives.<sup>4</sup>

- 29. Additionally, at all relevant times hereto, the GNC Defendants made and/or directly and affirmatively participated in, controlled, and/or adopted the false and misleading advertising and marketing claims about the Testofen Products. GNC also distributes the Testofen Products through its wholly-owned division, General Nutrition Centers, Inc., and owns and maintains websites, including www.GNC.com, through which it advertised, promoted and marketed the Testofen Products.
- 30. Further, at all relevant times, each of the Defendants were engaged in the design, manufacture, production, testing, study, inspection, labeling, marketing, advertising, sale, promotion and/or distribution of the Testofen Products.
- 31. Each of the Defendants acted jointly to perpetrate the acts described herein. At all relevant times alleged in this matter, each Defendant acted in concert with, with the knowledge and approval of and/or as the agent of the other Defendants within the course and scope of the agency, regarding the acts and omissions alleged.
- 32. The unfair, unlawful, deceptive, and misleading advertising and labeling of the Testofen Products relied upon by Plaintiffs were initiated, prepared and/or approved by Defendants and their agents, and was disseminated by Defendants and their agents through

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<sup>&</sup>lt;sup>4</sup> http://www.gnc.com/about-us.html (last visited Mar. 14, 2018).

manufacturing, marketing, advertising and/or labeling containing the misrepresentations alleged herein.

- 33. At all times relevant herein, Defendants and their subsidiaries, affiliates, and other related entities, as well as their respective employees, were the agents, servants, and employees of Defendants, and at all times relevant herein, each was acting within the purpose and scope of that agency and employment. Plaintiffs further allege on information and belief that at all times relevant herein, the distributors and retailers who delivered and sold the Testofen Products, as well as their respective employees, were Defendants' agents, servants, co-conspirators or partners, and at all times herein, each was acting within the purpose and scope of that agency and arrangement.
- 34. Additionally, Plaintiffs allege that, in committing the wrongful acts alleged herein, Defendants, in concert with their subsidiaries, co-conspirators, partners, affiliates, and/or other related entities and their respective employees, planned, participated in, and furthered a common scheme to induce members of the public to purchase the Testofen Products by means of misleading, deceptive, and unfair representations, and that Defendants participated in the making of such representations in that they disseminated those misrepresentations and/or caused them to be disseminated.

#### **JURISDICTION AND VENUE**

- 35. This Court has subject matter jurisdiction over this action because the amount in controversy exceeds the minimum jurisdictional limits of the Court.
- 36. Plaintiff Tommy Robbins is a resident of Missouri and purchased Testofen Products in Cole County, Missouri.

- 37. This Court has personal jurisdiction over Defendants pursuant to Missouri Code § 506.500, as Defendants have had more than sufficient minimum contact with the State of Missouri and have availed themselves of the privilege of conducting business in this state. Additionally, and as explained below, Defendants have committed affirmative tortious acts within the State of Missouri that give rise to civil liability, including distributing and selling the fraudulent Products throughout the State of Missouri.
- 38. Venue is proper in this forum pursuant to Rev. Stat. Missouri § 508.010, because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this county.

#### **ALLEGATIONS OF FACT**

#### BACKGROUND

#### A. TESTOSTERONE AND ANDROPAUSE

- 39. Testosterone is the principal male sex hormone and an anabolic steroid. Testosterone plays a large role in the health and well-being of men by maintaining sperm production, sex drive, muscle mass, and bone density. It is the hormone that is primarily responsible for producing and maintaining the typical male characteristics such as body and facial hair, muscle growth, and strength.
- 40. Maintaining normal testosterone levels in elderly men has been shown to improve parameters which are believed to cause cardiovascular disease risks, such as increased lean body mass and decreased cholesterol. Testosterone is also important for sustaining mental and physical energy.
- 41. Testosterone is produced mostly in the testes and a small amount of testosterone is produced from steroids secreted by the outer layer of the adrenal glands, also known as the adrenal cortex.

- 42. Testosterone primarily circulates in the blood of men in three types or forms. Most of the testosterone in the blood is bound to a protein called sex hormone binding globulin ("SHBG"). Testosterone is also bound to another protein called albumin. Testosterone that is not bound is considered "free."
- 43. The body carefully controls the production and regulation of testosterone. Chemical signals from two locations the pituitary gland at the base of the brain, and a part of the brain called the hypothalamus tell the testes how much testosterone to produce. The hypothalamus controls hormone production in the pituitary gland by means of gonadotropin-releasing hormone ("GnRH"). This hormone tells the pituitary gland to make follicle stimulating hormone ("FSH") and luteinizing hormone ("LH"). LH signals the testes to produce testosterone. If the testes begin producing too much testosterone, this is sensed by the brain which sends signals to the pituitary to make less LH. This, in turn, slows the production of testosterone. If the testes begin producing too little testosterone, the brain senses this and sends signals to the pituitary gland telling it to make more LH, which stimulates the testes to make more testosterone.
- 44. Furthermore, as men age, their ability to produce total, free, and bioavailable testosterone (*i.e.*, not bound by SHBG) gradually declines. This is due to a number of factors. For example, some men's production of LH decreases with age, which lowers testosterone production. Moreover, the protein that binds up and holds onto testosterone, SHBG, increases in older men. This reduces the amount of free (or unbound) testosterone in the blood that is available to tissues, such as muscles. Aging also causes changes in the daily cycle of testosterone production. For example, younger men show a spike or peak of testosterone levels in the morning, but this peak is reduced in older men.

- 45. "Andropause" is a term frequently used to describe this natural and subtle decline in testosterone production in men as they age. The most common symptoms of andropause include diminished sexual desire and erectile quality, low fertility rates, fatigue, depression, anxiety, irritability, increased body fat, and loss of strength and muscle mass. Complications associated with andropause include the risk of cardiovascular problems and osteoporosis.
- 46. It is estimated that the incidence of andropause in men from ages 50 to 59 is between 6 and 30 percent, with incidence increasing with age.
- 47. According to a 2006 study published in the *International Journal of Clinical Practice*, as many as 13.8 million men older than 45 in the United States have low levels of testosterone.
- 48. Medically diagnosed low testosterone levels are most often treated with a hormone replacement therapy, specifically testosterone replacement therapies ("TRTs"), which are prescribed to improve both physical and psychological functioning.
- 49. TRTs' regimens may only be conducted under the supervision of a licensed physician and require careful monitoring of hormone levels. TRT can consist of various forms of the hormone using delivery systems including patches, gels, creams, injections, or pellets.
- 50. TRT treatments, however, have a number of undesirable side effects and dangers. For example, prolonged use of any testosterone delivery system may result in breast enlargement, increased risk of prostate enlargement, or cancer in older men. Additionally, patients with preexisting heart, kidney, or liver disease may experience fluid accumulation with or without heart failure. Moreover, men with breast cancer or known or suspected prostate cancer should not receive testosterone therapy at all as it may increase the risks associated with these conditions.

51. Despite the risks, TRT treatments have seen a dramatic rise in use as the baby-boomer generation, which accounts for about 30 percent of the U.S. population, is beginning to feel the natural effects of low testosterone levels. In fact, treatments for low testosterone have exploded in the U.S., amounting to \$1.6 billion in sales in 2011 alone, according to data compiled by Bloomberg. Sales are expected to triple to \$5 billion by 2017, according to Global Industry Analyst, Inc.

#### B. DEFENDANTS CAPITALIZE ON THE BILLION DOLLAR TRT MARKET

- 52. In an effort to capitalize on the booming TRT market, Defendants began to market Testofen Products, and/or their ingredient Testofen, as "groundbreaking" supplements designed to boost testosterone levels. Moreover, as a result of this purported increase in testosterone, users would experience a number of benefits, including: improved orgasms, improved cognition, fat burning, or the promotion of fat loss, heightened libido, enhanced sexual performance, strengthened blood flow, promote or build muscle mass, improved power and/or stamina.
- 53. The Testofen Products consist primarily of a proprietary blend of small amounts of extracts from seeds, herbs, roots, and other organic substances. The main ingredient in Testofen Products is Testofen, a fenugreek seed extract that contains phytochemical constituents, including Furostanol and Saponins.
- 54. In marketing materials and on product packaging and labeling, Defendants claim the fenugreek seed extract, Testofen, contained in the Testofen Products is "proven" and "clinically demonstrated" to increase free testosterone levels.

#### C. FALSE AND MISLEADING MARKETING OF TESTOFEN PRODUCTS

- 55. Defendants engaged in a massive, uniform marketing and advertising campaign designed to convince consumers that Testofen Products, and the ingredient therein Testofen, naturally and dramatically boosts testosterone levels. Defendants then disseminated materially false and misleading statements which represent, both expressly and by implication, that scientific clinical tests prove the Testofen Products will dramatically boost testosterone levels and foster additional related benefits related thereto. These materially false, misleading, and deceptive statements were disseminated in a prolonged, multiplatform advertising and marketing campaign, labels and/or product packaging and in various media including industry periodicals, magazines, newspapers, television and internet media and or social/media.
- 56. This extensive and comprehensive advertising and marketing campaign was designed to induce consumers to purchase Testofen Products in reliance upon these representations and/or material omissions.

# 1. Force Factor

- 57. Force Factor primarily advertises and promotes their Test X180 Products through uniform labeling claims on the front of the Products' packaging. The label descriptions on the Test X180 Products' packaging, taken as a whole, represent there are various benefits and characteristics to the Test X180 Products including the ability to dramatically increase testosterone levels, burn fat, build muscle, boost sex drive and libido, and enhance performance. Moreover, that the Test X180 Products feature Gencor's Testofen ingredient, the purportedly "well-known, effective compound your body needs to combat natural testosterone decline."
- 58. Force Factor's Test X180 Products are also the subject of an extensive and comprehensive advertising and marketing campaign in various media including the internet

through ESPN, CNN, Yahoo sports, SI.com, healthheadlines.com, and on Defendant's own websites.

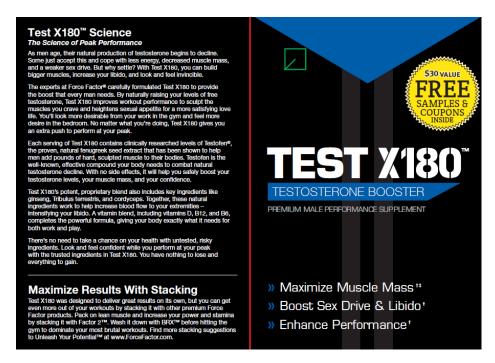
- 59. Defendant Force Factor advertises, distributes and sells the Test X180 Products directly to consumers online at www.forcefactor.com, www.testx180.com, and through nationwide retailers, including GNC stores and GNC's respective websites at www.gnc.com and www.Luckyvitamin.com.
- 60. Specifically, the front label of Text X180 features the misleading sub-headings "Boost Sex Drive & Libido," "Enhance Performance," "All-in-One Male Vitality Supplement," and "Free Testosterone Booster and Fat Burner."
- 61. Similarly, the side label states that Test X180 is a "premium Male Performance Formula" and that "with Text X180, you can build bigger muscles," "increase your libido," and heighten "sexual appetite for a more satisfying love life."
  - 62. Additionally, the side label further states:

Each serving of Test X180 contains clinically researched levels of Testofen®, the proven, natural fenugreek seed extract that has been shown to help men add pounds of hard, sculpted muscle to their bodies. Testofen is the well-known, effective compound your body needs to combat natural testosterone decline. With no side effects it will help you safely boost your testosterone levels, your muscle mass, and your confidence.

- 63. The label further boasts that the Test X180 Product is backed by real science by making claims such as:
- "The experts at Force Factor carefully formulated Test X180 ... with premium, clinically supported compounds like Testofen;"
- "The ingredients in our proprietary blend are substantiated with rigorous research and hard, scientific facts;"

- "Each serving of Test X180 contains clinically researched levels of Testofen®, the proven, natural fenugreek seed extract that has been shown to help men add pounds of hard, sculpted muscle to their bodies;"
- "Testofen is the well-known, effective compound your body needs to combat natural testosterone decline;" and
- "With no side effects, it will help you safely boost your testosterone levels."

  A copy of the label is reproduced below:



64. Force Factor's Test X180 Ignite product similarly features the misleading subheadings "Boost Sex Drive & Libido," "Enhance Performance," "All-in-One Male Vitality Supplement," and "Free Testosterone Booster and Fat Burner" on the front label. Moreover, the side label further states that Test X180 Ignite will increase "libido and performance" and "increase their sex drive" suggesting that Test X180 Ignite's ingredients work as advertised, *i.e.*, as a testosterone booster and aphrodisiac.

- 65. In addition, the side label states that "Test X180 Ignite was developed to be the ultimate all-in-one free testostorone booster, using safe, trusted ingredients backed by real science" and that "Test X180 Ignite is fueled by Testofen®, a natural fenugreek seed extract used by men worldwide."
- 66. Force Factor's Test X180 Alpha also features the misleading sub-headings "Heighten Libido," "Enhance Sexual Performance," "Strengthen Blood Flow," "Builds Lean Muscle Mass," "Maximize Power & Stamina," and "The prefered Testosterone Booster of Elite Men" on its front label. The Test X180 Alpha Products' label further states that "Alpha males don't settle for mediocrity," and that "Test X180 Alpha offers the complete solution for staggering virility, from dominating tough workouts in the gym to exceeding expectations in the bedroom" suggesting that the ingredients in Test X180 work as advertised, *i.e.*, as a testosterone booster and aphrodisiac.
- 67. Moreover, the Test X180 Alpha label 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 "With Test X180 Alpha, you'll start to transform your physique and have better sex. End of story."
- 68. Defendant Force Factor also makes similar misrepresentations on its website regarding the benefits of the Testofen Products as a testosterone booster. For example, Defendant's website with respect to Text X180 states:

How do you safely increase testosterone levels? Well-researched ingredients are the answer, which is why the experts at Force Factor® formulated Test X180<sup>TM</sup> with premium, clinically supported compounds like

Testosterone boosters aren't just for pro bodybuilders; they are the answer for every guy who wants to challenge his declining testosterone and perform at the highest level. Ready to feel like a superhero in the gym and in the

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.

bedroom? With Test X180, you can finally achieve maximum muscle gains, mind-blowing performance, and the explosive results you've been craving.

http://www.forcefactor.com/products/test\_x180 (last visited April 10, 2018).

69. Similarly, Force Factor's TestX180 Ignite website boasts the ability to boost testosterone levels, lean muscle mass, sex drive and libido. Specifically, the website states:

**Test X180 Ignite** – Natural Testosterone Builder That Improves Your Muscle Mass!

Test X180 is a revolutionary product that boosts your testosterone levels, which has wide ranging benefits for men of all ages. Rock hard muscles and sculpted abs are not reserved just for bodybuilders, you too can see these amazing results by simply purchasing Test X180 Ignite. Not only will your body transform, but your virility and sex drive will also benefit greatly.

http://testx180ignite.com/ (last visited April 10, 2018).

- 70. Similarly, Force Factor's TestX180 Alpha website boasts the ability to boost testosterone levels, "Heighten Libido," "Enhance Sexual Performance," "Strengthen Blood Flow," "Build Lean Muscle Mass," and "Maximize Power & Stamina." Furthermore, that "the natural ingredient Testofen® is clinically demonstrated to raise your body's free testosterone levels for dramatic increases in libido, strength, and stamina." http://forcefactor.com/products /test\_x180\_alpha (last visited April 10, 2018).
- 71. Furthermore, many of the Force Factor advertisements feature photographs of or quotations of physically fit and/or professional athletes lauding the benefits of TestX180 Ignite.

A screenshot captured from Force Factor's website featuring an image of an athlete and quotation from Vernon Davis, a professional NFL player, is provided below:



http://testx180ignite.com/ (last visited April 10, 2018).

72. Force Factor's website promoting a free trial of the Testofen Products makes similar representations. Screenshots captured from Force Factor's website featuring additional photographs and quotations from professional athlete Vernon Davis:







http://www.forcefactor.com/lg/15381/pid=180&aff\_id= (last visited April 10, 2018).

73. Additionally, Force Factor's materially false and misleading marketing campaign includes representations made on social media websites. For example, Force Factor states on the Facebook profile for Test X180<sup>5</sup> that Test X180 Ignite is "[t]he most advanced free testosterone booster yet." The Facebook page also maintains numerous photos and representations that Test X180 is a "natural" testosterone booster with "clinically researched ingredients" that will "Boost free testosterone by 99%":

 $<sup>^5 \</sup>textit{See} \ \text{https://www.facebook.com/pages/Test-180-Ignite/497345623687627} \ (last \ visited \ April \ 10, \ 2018).$ 



https://www.facebook.com/497345623687627/photos/pb.497345623687627.-2207520000.1416242283./502468336508689/?type=1&theater (last visited April 10, 2018).

74. Similarly, Force Factor's Twitter (July 13, 2015) page touts "The Science Behind Demonstrated Results".



<sup>&</sup>lt;sup>6</sup> https://twitter.com/search?q=test%20x180&src=typd (last visited April 10, 2018).

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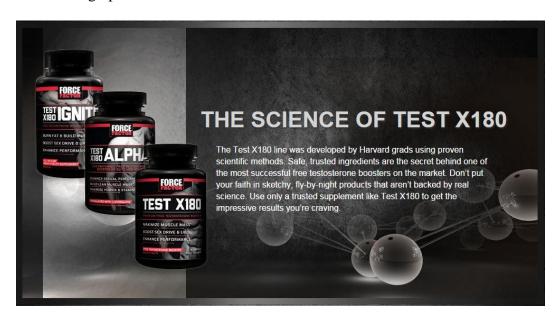
75. Defendant Force Factor also utilized video advertisements and commercials as a medium to disseminate misleading information. For example, Force Factor represents in video advertisements and commercials that Test X180 Ignite will dramatically increase free testosterone by 96%:



http://www.youtube.com/watch?v=sfXVMiYrcFg&index=2&list=UUYZPWYeZA4GJTeGf3xg HmHw (last visited April 10, 2018).

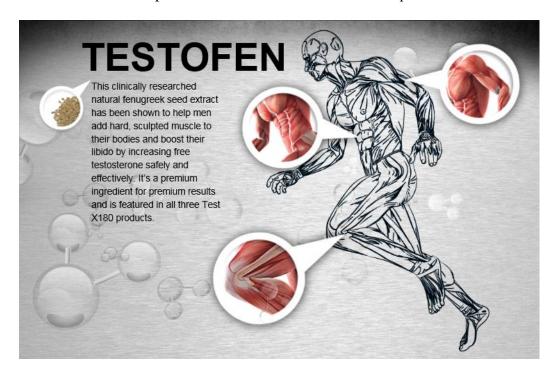
76. Moreover, Defendant Force Factor represents that Testofen Products are "backed by real science" and "substantiated with rigorous research and hard scientific facts" to boost testosterone levels, boost sex drive and libido, and are effective for their intended use. For example, Defendant claims the "Test X180 line was developed by Harvard grads using proven scientific methods." Furthermore, that Testofen, the purported active ingredient in Test X180 Product is "clinically researched" and has been shown to "help men add hard, sculpted muscle to

their bodies and boost their libido by increasing free testosterone safely and effectively." Force Factors use ornate graphics on its website to bolster the scientific claims:



http://www.testx180.com/science (last visited April 10, 2018).

77. Furthermore, Force Factor boasts the presence of "clinically researched" ingredients. A screenshot captured from Force Factor's website is provided below:



http://www.testx180.com/science (last visited April 10, 2018).

78. Similarly, Force Factor states on its website that the Testofen Products are "substantiated with rigorous research and hard, scientific facts." Accordingly:

How do you safely increase testosterone levels? Well-researched ingredients are the answer, which is why the experts at Force Factor® formulated Test  $X180^{TM}$  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.

79. Force Factor also maintains a section on its website titled "Test X180 Ignite-Does it Really Work?" reinforcing the misrepresentation that Testofen Products are "clinically proven":

If you are looking to boost your testosterone naturally using a clinically proven safe method, you should try <u>Test X180 Ignite</u>. This testosterone booster works quickly to make you not only feel younger, but also help your body work more efficiently at creating muscle mass. This product will help you make the most out of your workouts and even allow your body to recover at record rates.

This product is completely safe and studies show that no side effects are caused by use of this testosterone booster. Test X180 Ignite is created using a formula that was expertly crafted to yield real results for all users.

http://testx180ignite.com (last visited April 10, 2018).

80. Similarly, Force Factor has created and sponsored a multitude of affiliated websites touting that Testofen Products and its ingredients are purportedly backed by significant funding and "years" of scientific research. For example, www.healthheadlines.com states:

Introducing Testofen. After years of research and millions of dollars spent, scientists agree that this game-changing ingredient formulated from a natural fenugreek seed extract is the best way to boost free testosterone and get an insane boost in libido. We've tested it personally and believe us; it's worth the hype.

http://www.healthheadlines.com/fitness/test-x180-a-brand-new-supplement-hits-the-shelves-24\_7898/ (last visited April 10, 2018).

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<sup>&</sup>lt;sup>7</sup> http://www.forcefactor.com/products/test\_x180 (last visited Sept. 3, 2015).

# 2. <u>Direct Digital</u>

- 81. Defendant Direct Digital has engaged in a massive, uniform marketing and advertising campaign designed to convince aging consumers that the Testofen Products sold under the Nugenix brand naturally and dramatically boost testosterone levels. Direct Digital then disseminated materially false and misleading statements which represent, both expressly and by implication, that scientific clinical testing proves that Nugenix will dramatically boost testosterone levels. These false and misleading statements were disseminated on Nugenix Products' labels, in advertising, marketing, and promotional materials designed to induce consumers to purchase the Nugenix Products through the internet and through national retailers such as GNC stores.
- 82. For example, the front label of Nugenix Natural Testosterone Booster features the misleading sub-headings "Libido," "Strength," "Stamina" and "Vitality." The front label further states that Nugenix "helps to Feel Stronger, Increase Sex Drive, and Boost Free Testosterone."



- 83. The side label further boasts that the Nugenix Natural Testosterone Product is effective and clinically studied by making claims such as:
  - "Nutritional Developers formulated Nugenix with Testofen®, a key natural ingredient to help boost 'free' testosterone along with resistance training. This key ingredient is extracted from the fenugreek plant."
  - "A Testofen® study in Irvine, California indicated positive free testosteronerelated results;"
  - "Nugenix also includes L-Cituline Malate, Tribulus, Zinc, plus Vitamins B6 and B12 to help promote overall health and performance;"
  - "Nugenix's main ingredients can help improve your sexual performance and help promote overall health. Nugenix can also help you enjoy time with your partner;" and
  - "Try Nugenix along with your exercise program right now and gain the benefits of potentially boosting the all-important 'free' testosterone."
- 84. Similarly, the front label of Nugenix Ultimate Testosterone Product features the misleading sub-headings that it is an "Advanced Free Testosterone Complex" that "helps to Boost Free Testosterone, Maximize Muscle Growth, Increase Drive and Vitality, and Modulate Androgenic Activity. A copy of the product packaging featuring these misrepresentations is provided below:



- 85. The side label of Nugenix Ultimate Testosterone Booster further boasts:
  - "Nugenix Ultimate is a no fluff, hardcore, complex free testosterone formula designed to be taken only as directed and for people who are looking for serious testosterone support in their lifestyle and in the gym."
  - "Contains 8 key ingredients designed to help boost free testosterone, maximize muscle growth, increase drive, and help modulate androgenic activity."
- 86. Direct Digital's Nugenix website is also replete with misleading advertisements touting the ability to boost testosterone levels, vitality, and libido. For example, the website states:

#### **Boost Free Testosterone with Nugenix**

See why Nugenix is the #1 selling Men's Vitality product at GNC stores and Winner of GNC'S 2013 Innovation Award!<sup>8</sup>

87. Defendants' website also claims "Taking Nugenix is safe, easy, and effective..."9



88. Direct Digital also make similar misleading representations in video advertisements and commercials. For example, Direct Digital states that Nugenix is a "Powerful

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<sup>&</sup>lt;sup>8</sup> http://www.nugenix.com/ (last visited April 10, 2018).

<sup>&</sup>lt;sup>9</sup> Id.

Man-Boosting Innovation" that will address "Lower Sex Drive," "Sluggishness," and "Decreased Performance" by providing "Increased Libido," "Higher Sex Drive," and "Improved Performance." Screenshots from the video advertisement featuring these misrepresentations are provided below:

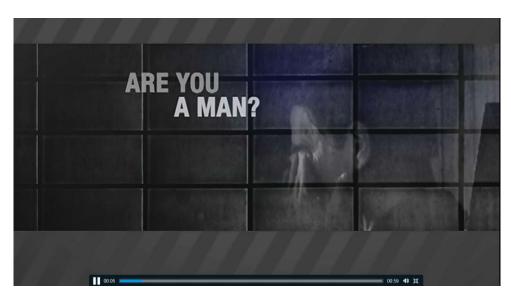




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<sup>&</sup>lt;sup>10</sup> http://www.ispot.tv/ad/7lI7/nugenix-natural-testosterone-booster (last visited April 10, 2018)

89. Another video advertisement touts that the Nugenix Products are "Powerful", "All-Natural", and "Clinically Tested" to "Increase Libido" and provide increased energy and performance. Screenshots from the video advertisement featuring these misrepresentations are provided below:





<sup>&</sup>lt;sup>11</sup> http://www.ispot.tv/ad/7dIG/nugenix (last visited April 10, 2018)



90. To further bolster these misrepresentations, many of the advertisements feature photographs of physically fit athletes lauding the benefits of Nugenix:<sup>12</sup>



<sup>&</sup>lt;sup>12</sup> https://www.nugenix.com/trial/ (last visited April 10, 2018).

# KEEP YOUR ADVANTAGE AND GAIN AN EDGE







# YOU CAN FIGHT BACK WITH NUGENIX.

Get Ready to maintain your edge with the help of Nugenix. Boston-based nutritional developers created Nugenix to help men maintain a youthful edge... in the bedroom... in the workplace... in the gym.

Nugenix is a PREMIUM dietary supplement carefully blended to help boost the all-important free testosterone. Nugenix has become a daily choice for men who enjoy full vitality and libido - and want to keep it that way. It's also chosen by men who want to gain an edge with a strong sex drive and better performance.

Nugenix was the #1 best selling men's vitality product in GNC stores in the United States for 2013 for a reason!

Explore the benefits of boosting your free testosterone with Nugenix on your side.

91. Additionally, Direct Digital's false and misleading marketing campaign includes representations made on various social media websites. For example, on the Facebook profile for Nugenix, Defendant states that Nugenix is "a safe and specially formulated all-natural dietary supplement that helps your body increase its natural production of testosterone." The Facebook page also maintains numerous photos and representations that Nugenix is effective at boosting testosterone:



<sup>&</sup>lt;sup>13</sup>https://www.facebook.com/152163308260627/photos/a.152164414927183.46893.152163308260627/3915376976 56519/?type=1&theater (last visited April 10, 2018).

# 3. Pharmafreak

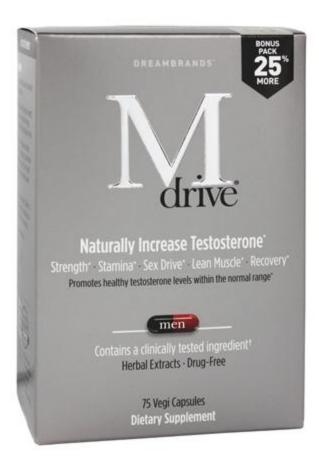
92. Pharmafreak primarily advertises and promotes its Testfreak Products through uniform labeling claims on the front of the Products' packaging. Label descriptions on the Products' packaging, taken as a whole, represent there are various benefits and characteristics to the Products including the ability to dramatically increase testosterone levels, burn fat, build muscle, boost sex drive and libido, and enhance performance. For example, the front label of the Testfreak product states that it is a "Hybrid Pro-Testosterone Stimulator" that contains "Pro Testosterone Compounds." The front label further touts that the Testfreak Product "Helps Increase Free Testosterone," "Helps Increase Total Testosterone," and that it "Promotes Sex Drive and Libido." Copies of the Testfreak Product labels are reproduced below:





## 4. Dreambrands

- 93. Dreambrands primarily advertises and promotes its Mdrive and Mdrive Elite Products through uniform labeling claims on the front of the Products' packaging. Label descriptions on the Products' packaging, taken as a whole, represent there are various benefits and characteristics to the Products including the ability to dramatically increase testosterone levels, burn fat, build muscle, boost sex drive and libido, and enhance performance.
- 94. For example, the front label of the Mdrive Product states that it "Naturally Increase[s] Testosterone," "Strength," "Stamina," "Sex Drive," "Lean Muscle" and "Recovery." The front label of the Mdrive Product further states that it "contains a clinically tested ingredient." A copy of the Mdrive Product label is reproduced below:



- 95. The front label of the Mdrive Elite Product touts it provides "Endurance" and "Recovery" "with Energizing Testosterone Support." In addition, the front label states that the Product with "Maximize sustained energy," "Reduce body fat and preserve lean muscle," "Maintain healthy cortisol levels & reduce stress" and will "Speed muscle recovery" with "5 Clinically Tested ingredients."
- 96. The side label of the Mdrive Elite Product states that it contains a "Prime Drive Formula" and that the Product provides "Energy, Stamina, and Vitality" and that it will "Reduce Body Fat." A copy of the Mdrive Elite Product label is reproduced below:



# 5. Kingfisher

- 97. Kingfisher primarily advertises and promotes its HighT line of products through uniform labeling claims on the front of the Products' packaging. Label descriptions on the Products' packaging, taken as a whole, represent there are various benefits and characteristics to the Products including the ability to dramatically increase testosterone levels, build muscle, boost sex drive and libido, and enhance performance.
- 98. For example, the front labels of the HighT Products state that it is a "Testosterone Booster" that is "Scientifically Formulated" to promote "Sex Drive & Libido," "Strength & Stamina," and "Energy & Vitality." Below are screenshots of the front labels of the HighT, High

T Senior, High T Black Hardcore Formulation and High T Black Caffeine Free Hardcore Formulations:



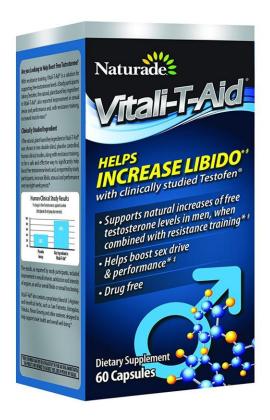






#### 6. Naturade

- 99. Naturade primarily advertises and promotes its Vitali-T-Aid Products through uniform labeling claims on the front of the Products' packaging. Label descriptions on the Products' packaging, taken as a whole, represent there are various benefits and characteristics to the Products including the ability to dramatically increase testosterone levels, burn fat, build muscle, boost sex drive and libido, and enhance performance.
- 100. For example, the front label of the Vitali-T-Aid states that it "Helps Increase Libido with clinically studied Testofen" and that it "Supports natural increase of free testosterone levels in men, when combined with resistance training" and that it "Helps boost sex drive & performance."
- 101. The side label of the Vitali-T-Aid states that "With resistance training, Vitali-T-Aid is a solution for supporting free testosterone levels. Study participants taking Testofen, the natural, plant based key ingredient in Vitali-T-Aid, also reported improvement in sexual desire and performance and, with resistance training, increased muscle mass." The side label further states that Vitali-T-Aid contains a "Clinically Studied Ingredient" and that "The natural, plant based key ingredient in Vitali-T-Aid was shown in two double-blind, placebo-controlled, human clinical studies, along with resistance training, to be a safe and effective way to significantly help boost free testosterone levels and, as reported by study participants, increase libido, arousal and performance over an eight week period." A copy of the Vitali-T-Aid product label is reproduced below:



102. Similarly, Naturade's website boasts that clinical study participants reported that a certain natural, plant based key ingredient "Promotes Healthy Libido" and "Supports Healthy Erectile Functions." https://www.naturade.com/shop-online/naturade-vitali-t-aid/ (last visited April 10, 2018).

## 7. **GNC Defendants**

103. The GNC Defendants participated in, controlled, adopted and/or reinforced the false and misleading advertising claims about Testofen Products, by among other things: (1) displaying Testofen Products and their false packaging claims on their store shelves; (2) utilizing false and misleading in-store Testofen Products advertisements, displays and/or exhibits; (3) displaying Testofen Products and their false packaging claims on the GNC branded website,

including pictures of the false and deceptive packaging and labeling of the Testofen Products on its websites; (4) making statements on their websites that repeated and reinforced the false and misleading statements contained on the packaging and labeling of the Testofen Products; (5) reviewing and approving false and misleading advertising materials for promoting the sale of Testofen Products, including advertisements that bore the retailers' names, logos and/or trademarks; and (6) selling Testofen Products to end users in the United States including in Missouri.

#### a. Retail Displays

- 104. The GNC Defendants have more than 6,500 stores nationwide operating under the GNC brand name.
- 105. The GNC Defendants' retail stores have standardized point-of-sale displays that include shelf signage, floor displays and checkout displays.
- 106. In 2009, for example, the GNC Defendants announced plans to carry Force Factor's line of products on its store shelves. *See* http://www.forcefactor.com/news/gnc (last visited April 10, 2018).
- 107. The GNC Defendants display Testofen Products and their false packaging claims on store shelves, and also utilize false and misleading in-store Testofen Products advertisements, displays and/or exhibits to sell Testofen Products to end users in retail stores.

#### b. Relationship with Certain Brand Defendants

108. In fact, GNC provides substantial assistance to various Brand Defendants by allowing them to capitalize on GNC's brand recognition and reputation, which holds itself out as "set[ting] the standard in the nutritional supplement industry by demanding truth in labeling,

ingredient safety and product potency."<sup>14</sup> For example, the GNC Defendants are repeatedly featured in the marketing and advertising of Testofen Products, which represents to consumers that Testofen Products can be purchased from a trusted source, GNC.<sup>15</sup> A screenshot of Force Factor's website illustrating this symbiotic relationship is provided below:<sup>16</sup>



109. Moreover, in 2009, the GNC Defendants awarded Force Factor the GNC's Rising Star Award, an accolade that Force Factor consistently touts as a testament to its success. <sup>17</sup>



#### c. GNC's Websites

- 110. The GNC Defendants repeated and reinforced the false and misleading advertising of Testofen Products by similarly attesting to the abilities of Testofen Products. For example, GNC's website notes that Test X180 has the ability to (1) "Maximize Muscle Mass," (2) "Boost Sex Drive & Libido," and (3) Enhance Performance." 18
- 111. The GNC Defendants incorporated or adopted marketing and advertising language from Brand Defendants. For example, GNC Defendants made specific representations concerning the "Science" behind Force Factor's Test X180 product to bolster the alleged benefits of use, stating: "Each serving of Test X180 contains clinically researched levels of Testofen the

<sup>&</sup>lt;sup>14</sup> http://gnc.mediaroom.com/ ((last visited April 10, 2018).

https://www.gnc.com/Force-Factor-Test-X180-IGNITE/product.jsp?productId=23933156 (last visited April 10, 2018).

<sup>&</sup>lt;sup>16</sup> https://www.forcefactor.com/store locator (last visited April 10, 2018).

<sup>&</sup>lt;sup>17</sup> https://www.forcefactor.com/wholesale (last visited April 10, 2018).

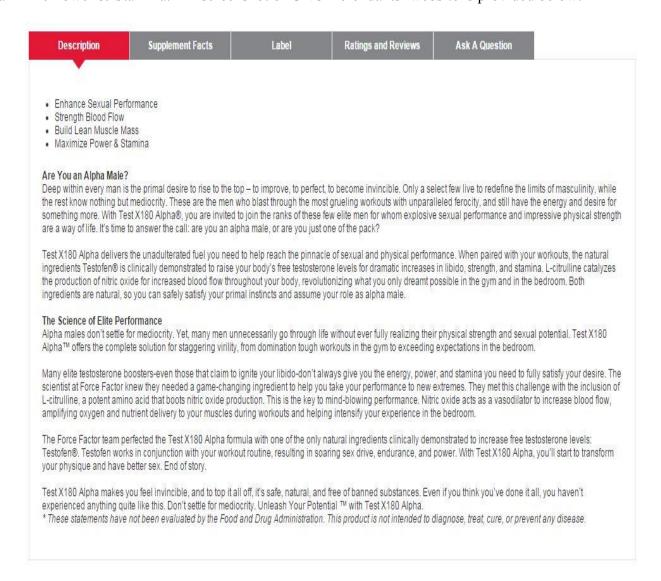
<sup>&</sup>lt;sup>18</sup> http://www.gnc.com/Force-Factor-Test-X180/product.jsp?productId=12737631 (last visited April 10, 2018).

proven, natural fenugreek seed extract that has been shown to help men add pounds of hard, sculpted muscle to their bodies. Testofen is the well-known, effective compound your body needs to combat natural testosterone decline." A screenshot of GNC Defendants' website is provided below: 19

Description	Supplement Facts	Label	Ratings and Reviews	Ask A Question	
Maximize Muscle Ma     Boost Sex Drive & Li     Enhance Performance	bido				
	rformance Il production of testosterone begli t X180, you can build bigger mus			ergy, decreased muscle mas	s, and a weaker sex drive.
improves workout perfor	ctor® carefully formulated Test X1 mance to sculpt the muscles you esire in the bedroom. No matter v	crave and heightens sexu	ual appetite for a more satisfying	love life. You'll look more de	
hard, sculpted muscle to	30 contains clinically researched their bodies. Testofen is the well ur testosterone levels, your musc	-known, effective compou	ind your body needs to combat r		
	rietary blend also includes key in our extremities – intensifying your both work and play.				
	a chance on your health with unt thing to lose and everything to ga		ook and feel confident while you	u perform at your peak with th	e trusted ingredients in
on lean muscle and increworkouts.	I to deliver great results on its ow ease your power and stamina by	stacking it with Factor 2™	'. Wash it down with BRX™ befo	re hitting the gym to dominate	e your most brutal
* These statements have	not been evaluated by the Food	and Drug Administration.	. This product is not intended to	diagnose, treat, cure, or preve	ent any disease.

<sup>19</sup> http://www.gnc.com/Force-Factor-Test-X180/product.jsp?productId=12737631 (last visited April 10, 2018).

112. Similarly, the GNC Defendants advertise Test X180 Alpha as a product that can "Enhance Sexual Performance," "Strength[en] Blood Flow," "Build Lean Muscle Mass," and "Maximize Power & Stamina." A screenshot of GNC Defendants' website is provided below:<sup>20</sup>

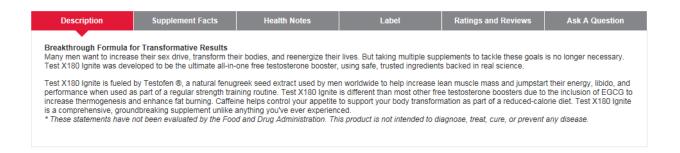


113. The GNC Defendants further proclaim that Test X180 Alpha, "[w]hen paired with your workouts, the natural ingredient Testofen is clinically demonstrated to raise your body's free testosterone levels for dramatic increases in libido, strength and stamina."<sup>21</sup>

<sup>20</sup> http://www.gnc.com/Force-Factor-Test-X180-ALPHA/product.jsp?productId=16633956 (last visited April 10, 2018).

http://www.gnc.com/Force-Factor-Test-X180-ALPHA/product.jsp?productId=16633956 (last visited April 10, 2018).

114. With respect to Force Factor's Test X180 Ignite product, the GNC Defendants noted it was a "[b]reakthrough [f]ormula for [t]ransformative [r]esults," and "was developed to be the ultimate all-in-one testosterone booster, using safe, trusted ingredients backed in real science" and "is fueled by Testofen®, a natural fenugreek seed extract used by men worldwide to help increase lean muscle mass and jumpstart their energy, libido, and performance." A screenshot of the GNC Defendants' website is provided below: <sup>23</sup>



115. The GNC Defendants also maintain copies of the Brand Defendants' Testofen Product labels. For example, GNC maintained copies of the Test X180, <sup>24</sup> Test X180 Alpha, <sup>25</sup> and Test X180 Ignite<sup>26</sup> product labels on their website:

<sup>-</sup>

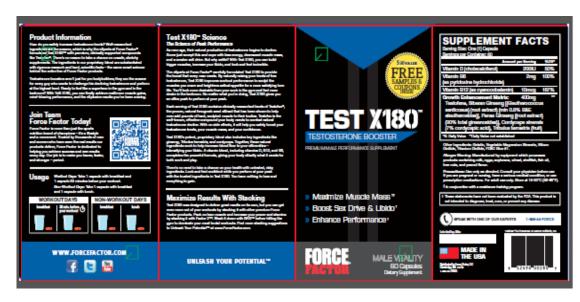
<sup>&</sup>lt;sup>22</sup> http://www.gnc.com/Force-Factor-Test-X180-IGNITE/product.jsp?productId= 23933156 &green= 4F5A2E18-25A9-5361-A228-89812B39A38C (last visited April 10, 2018).

http://www.gnc.com/Force-Factor-Test-X180-IGNITE/product.jsp?productId=23933156 (last visited April 10, 2018).

<sup>&</sup>lt;sup>24</sup> http://www.gnc.com/graphics/product\_images/pGNC1-12488894\_gnclabel\_pdf.pdf (last visited April 10, 2018).

<sup>&</sup>lt;sup>25</sup> http://www.gnc.com/graphics/product\_images/pGNC1-14403129\_gnclabel\_pdf.pdf (last visited April 10, 2018).

<sup>&</sup>lt;sup>26</sup> http://www.gnc.com/graphics/product\_images/pGNC1-16783859\_gnclabel\_pdf.pdf (last visited April 10, 2018).





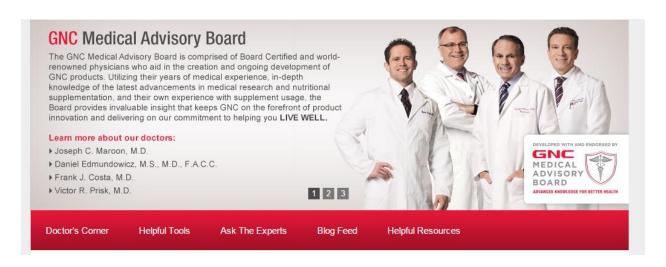


of Testofen Products were false, misleading and baseless.<sup>27</sup> According to the GNC Defendants, "[f]rom our scientific research and new product discovery to our manufacturing and packaging processes and finally our interaction with customers in our stores, everything GNC does is done with rigorous quality."<sup>28</sup> In fact, GNC maintains a medical advisory board, which according to the GNC Defendants, "utilizes their in-depth medical knowledge and experience to aid in the creation and ongoing development of GNC products, helping GNC stay on the forefront of product innovation and delivering on our commitment to helping you LIVE WELL."<sup>29</sup> A screenshot of GNC Defendant's website is provided below:<sup>30</sup>

<sup>&</sup>lt;sup>27</sup> This information is solely within GNC's possession.

<sup>&</sup>lt;sup>28</sup> GNC Holdings, Inc. Code of Business Conduct and Ethics at iii, *available at* http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9MTc0ODE3fENoaWxkSUQ9LTF8VHlwZT0z&t=1 (last visited April 10, 2018).

<sup>&</sup>lt;sup>29</sup> https://www.gnc.com/graphics/product\_images/pGNC1-13402640\_gnclabel\_pdf.pdf (last visited April 10, 2018). <sup>30</sup> http://www.gnclivewell.com/MAB/ (last visited April 10, 2018).



94. GNC has also developed their own line of testosterone boosters called "Healthy Testosterone Formula," which contains, among other ingredients, Testofen as its single largest ingredient. GNC states on product packaging that its "Healthy Testosterone Formula," product featuring Testofen was scientifically developed utilizing the expertise of (and endorsed by) GNC's "Medical Advisory Board." Not surprisingly, GNC represents that its Healthy Testosterone Formula featuring Testofen is clinically shown to: improve sexual health, blood flow and optimal vitality; fuels lean muscle mass & supports a healthy metabolism, and is designed to support testosterone levels that decline with age. Similarly, GNC developed "Beyond Raw Re Test Hardcore Anabolic Enhancer," also featuring Testofen, which purportedly "[s]upports [h]ealthy [t]estosterone [l]evels." GNC's "Medical Advisory Board," composed of "world renowned" Board Certified physicians, knew or should have known that the sale and promotion of Testofen Products are false and misleading and baseless. Regardless, GNC buries an admission in its website that states: "[i]n men, testosterone levels peak in young childhood

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<sup>&</sup>lt;sup>31</sup> http://www.gnc.com/GNC-Preventive-Nutrition-Healthy-Testosterone-Formula/product.jsp?productId= 22738816 (last visited April 10, 2018).

http://www.gnc.com/GNC-Beyond-RAW-RE-TEST/product.jsp?productId=22750216 (last visited April 10, 2018).

and decline over time. A number of supplements are marketed as natural testosterone support, though the effects have not been demonstrated in clinical research."<sup>33</sup>

#### 8. Gencor Defendants

117. Gencor Defendants manufacture the herbal ingredient Testofen, a standardized extract of Trigonella foenum-graecum (more commonly known as fenugreek). Defendants market and sell the ingredient Testofen as "proven" testosterone boosters to numerous sports nutrition companies that manufacture nutritional supplements.

118. For example, on Gencor's website, the Gencor Defendants tout the purported benefits and market opportunity for the ingredient, stating, "Incorporate Testofen in product formulations designed to support healthy sexual function and performance in adult males." The page also features a video clip of Gencor's Chief Scientific Advisor, Paul Clayton, Ph.D., discussing the purported benefits of taking Testofen. A screenshot from Defendants' website is reproduced below: <sup>35</sup>

<sup>&</sup>lt;sup>33</sup> http://www.gnc.com/Force-Factor-Test-X180/product.jsp?productId=12737631 (last visited April 10, 2018). <sup>34</sup> https://youtu.be/NL\_4G13Y1is (last visited April 10, 2018).

<sup>35</sup> http://www.gencorpacific.com/index.php/featured-ingredients/testofen (last visited April 10, 2018).



- 119. Gencor Defendants state, "Gencor provides clinically proven ingredients formulated to support your customer's specific lifestyle health issues." http://www.gencorpacific.com/index.php/featured-ingredients (last visited April 10, 2018).
- 120. When Gencor marketed the sale of Testofen, Gencor publicly released information about the purported and "proven" benefits of Testofen with knowledge, reason to know, and/or intent that the information would be repeated by sellers of the Testofen Products, and consumers purchasing the Testofen Products would rely on the information.
- 121. In doing so, the Gencor Defendants supplied the false and misleading information regarding alleged efficacy of Testofen to Brand Defendants and the GNC Defendants who

ultimately marketed and sold the ineffective products to unsuspecting consumers. Gencor is, therefore, equally liable to consumers as the other Defendants.

122. To facilitate this misleading conduct, Gencor Defendants also released a video featuring Dr. Paul Clayton-Chief Scientific Advisor at Gencor, suggesting that Testofen is similar in structure to a "steroidal hormone" and will in fact result in "a doubling of free testosterone levels." An excerpt from the transcript of the promotional video is provided below:

Testofen is a standardized extract from the culinary herb fenugreek. Uh it's very carefully extracted and standardized to its content of fenusides: these are saponins which means that they have a molecular structure a little bit like a steroid hormone.

When you ingest these, they're enough like a steroid hormone to bind to a protein in the blood called sex hormone binding globulin. And when that happens, a very small percentage of the testosterone that's bound to this protein is released and activated.

This results in approximately a doubling of free testosterone levels. Now that's important because as we get older, 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, uh, 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 charges are reversed. And what we've shown in a number of studies is that when combined with exercise, this leads to increased muscle building. And in a very interesting double-blind randomized clinical trial that we carried out in Australia [inaudible stumbling on words] that we found that there was very dramatic improvements in libido, sexual performance, sexual satisfaction in a group of young to middle-aged males.

This is a very interesting product because I think the first time we have something that genuinely enhances sexual function and sexual desire. Now the drugs like Viagra which inhibit the enzyme phosphodiesterase, a pde5, act on the hydraulic elements if you will, of male sexuality, but they don't have any impact on women. And although these are used as party

<sup>&</sup>lt;sup>36</sup> http://www.gencorpacific.com/index.php/featured-ingredients/testofen (last visited April 10, 2018).

drugs, they're not very good for couples, in fact they've been very destructive in many cases of long-established relationships.

What we have here is a compound that enhances sexual desire, libido, in both males and we're now finding in females too. So this is very much a supplement, a herb that couples can take and um a remedy perhaps for the seven year itch.

123. Additionally, Gencor lists on its website "approved health claims for the ingredient, Testofen: "supports healthy levels of free testosterone," "promotes sexual desire and vitality," "reduces recovery time following sexual activity," "supports muscle mass," and "promotes healthy energy levels." A screenshot from Gencor's website is reproduced below:<sup>37</sup>



# Approved health claims

The following structure-function claims for Testofen® are provided here for informational purposes only and should be reviewed by your legal counsel prior to use in marketing materials, including product labels.

- Supports healthy levels of free testosterone\*
- Promotes sexual desire and vitality\*
- Reduces recovery time following sexual activity\*
- Supports muscle mass\*
- Promotes healthy energy levels\*
- Helps reduce normal symptoms of Andropause in men over age 40\*

<sup>&</sup>lt;sup>37</sup> http://www.gencorpacific.com/index.php/featured-ingredients/testofen (last visited April 10, 2018).

124. These misrepresentations are substantially similar, if not identical, to the misrepresentations that appear on some of the Brand Defendants websites. For example, the chart below compares the authorized claims on Gencor's website with the claims that appear on the label of Force Factor's TEST X180 Product:

#### **GENCOR WEBSITE**

The following structure-function claims for Testofen® are provided here for informational purposes only and should be reviewed by your legal counsel prior to use in marketing materials, including product labels.

- Supports healthy levels of free testosterone\*
- Promotes sexual desire and vitality\*
- Reduces recovery time following sexual activity\*
- Supports muscle mass\*
- Promotes healthy energy levels\*
- Helps reduce normal symptoms of Andropause in men over age 40\*

## TEST X180 LABELING

- "Safely boost your testosterone levels"
- "Boost Sex Drive & Libido"
- "Boosts vitality"
- "Enhance Performance"
- "Maximize muscle mass"

125. Similarly, Gencor Defendants maintain references to clinical research on their website, with knowledge, reason to know, and/or intent that the information would be repeated by sellers of the Product and consumers purchasing the Products would rely on the information repeated by such sellers. For example, Defendants cite to several misleading studies, including by Sachin Wankhede, Vishwaraman Mohan and Prasad Thakurdesai (the "Pilot Study"), stating "the active group" in the Pilot Study displayed a range of "mainly statistically significant results." *See* http://www.gencorpacific.com/index.php/featured-ingredients/testofen (last visited April 10, 2018). Additionally, Gencor states on its website that results from the Pilot Study demonstrate, among others, "[s]ignificant support for free testosterone (p<0.05) compared to

placebo group."<sup>38</sup> Many of the Brand Defendants parrots these claims in its marketing materials. For example, Force Factor's website states:

- "The ingredients in our proprietary blend are substantiated with rigorous research and hard, scientific facts;"
- "Each serving of Test X180 contains clinically researched levels of Testofen®, the proven, natural fenugreek seed extract that has been shown to help men add pounds of hard, sculpted muscle to their bodies;"
- "Testofen is the well-known, effective compound your body needs to combat natural testosterone decline;"

# D. THE TESTOFEN PRODUCTS AND THE ACTIVE INGREDIENTS THEREIN, INCLUDING TESTOFEN, DO NOT BOOST TESTOSTERONE LEVELS

- 126. Dietary supplements are governed by the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). Pursuant to DSHEA, a supplement manufacturer may only make claims concerning how a product affects the structure or function of the body without obtaining prior FDA approval if certain requirements are met, including that the manufacturer is able to substantiate that the claims are truthful and not misleading. 21 U.S.C. § 343(r)(6)(B).
- 127. Further, the FDA has adopted the FTC's substantiation standard of "competent and reliable scientific evidence" for dietary supplements.
- 128. The universally accepted form of scientific evidence recognized by experts in the field for determining whether a substance provides any human health benefit is by demonstrating its value over placebo through high-quality and well-conducted randomized controlled clinical trials ("RCTs"). Also, it is generally recognized that RCTs that are of sufficient quality to be relied upon for reaching efficacy conclusions should be subjected to a peer review process and published in a peer-reviewed journal.

<sup>&</sup>lt;sup>38</sup> http://www.gencorpacific.com/index.php/featured-ingredients/testofen (last visited April 10, 2018).

- 129. Competent and reliable scientific evidence is defined as: "tests, analysis, research, studies, or other evidence based on the expertise of professionals in the relevant area that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." For products such as Testofen, adequate substantiation, as required by experts in the relevant area, consists of high-quality RCTs—particularly when representations regarding health effects is the subject matter.
- 130. Despite this clear standard, Defendant has not performed any reliable or high-quality RCTs substantiating its representations about Testofen.
- 131. Rather, Gencor Defendants prominently displayed and/or referenced several studies on Gencor's website to represent that Testofen, the active ingredient in the Testofen Products is "proven' and/or "clinically demonstrated to dramatically increase free testosterone levels in the human male, by upwards of 96%," thereby "boost[ing] sex drive and libido," "enhanc[ing] performance," and increasing "lean muscle mass."
- 132. For example, Gencor cites to a study titled "Human Study on Free Testosterone and Performance" to demonstrate, among others, "[s]ignificant support for free testosterone (p<0.05) compared to placebo group" (the "Pilot Study."). A screenshot from Defendants' website is reproduced below: 40

<sup>&</sup>lt;sup>39</sup> Wankhede S, Mohan V, Thakurdesai P, Beneficial effects of fenugreek glycoside supplementation in male subjects during resistance training: a randomized controlled pilot study, Journal of Sport and Health Science (2015), doi: 10.1016/j.jshs.2014.09.005.

<sup>&</sup>lt;sup>40</sup> http://www.gencorpacific.com/index.php/featured-ingredients/testofen (last visited April 10, 2018).

#### Human study on free testosterone 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 mainly statistically significant results:

- Significant anabolic activity as evidenced by BUN reduction (p<0.05) compared to placebo\*
- Significant support for free testosterone (p<0.05) compared to placebo</li> group'
- Immune support (p<0.003) compared to placebo group\*</li>
- Significant support for Serum Creatinine levels (p<0.02) compared to placebo group signifying support for Creatine uptake and recycling in muscle cells'
- Significant support for prolactin (p<0.04) compared to placebo group,</li> however, this increase is within physiological limits for men'
- Significant decrease in body fat compared to baseline\*
- Supports maintenance of muscle size despite maintaining overall weight and reduction of body fat\* (although not significant)

Citation: Wankhede S, Mohan V, Thakurdesai P, Beneficial effects of fenugreek glycoside supplementation in male subjects during resistance training: a randomized controlled pilot study, Journal of Sport and Health Science (2015), doi: 10.1016/j.jshs.2014.09.005.

- 133. Similarly, Gencor Defendants rely on a 2010 study of Testofen on the reproductive systems of male albino rats to suggest that Testofen supported an increase in the weight of the ani-levator muscle, which led to support for muscle mass and body weight (the "Aswar Study.").41
- Lastly, Gencor Defendants rely on a 2009 study entitled 42 "Human Study on Adult Male Sexual Desire" enrolling 60 adult males utilizing a formulation containing Testofen as a major ingredient to suggest a "statistically significant increase in the sexual function, performance and satisfaction of the active group" (the "Steels Study."). 43
- 135. Defendants, however, misrepresent the results from these clinical trial(s). In other words, the results cited by and relied upon by the Defendants in support of their advertising claims do not actually support the proposition for which the studies are cited.

<sup>&</sup>lt;sup>41</sup> Urmila Aswar et.al, 2010. Effect of Furostanol Glycosides from Trigonella foenum –graecum on the reproductive

system of Male Albino Rats. Phytotherapy Research, 24, 1482–1488.

42 Steels, E., Rao, A. and Vitetta, L., 2011. Physiological Aspects of Male Libido Enhanced by Standardized Trigonella foenum-graecum Extract and Mineral Formulation. Phytotherapy Research, Vol. 25, 1294-1300. doi: 10.1002/ptr.3360.

<sup>&</sup>lt;sup>43</sup> http://www.gencorpacific.com/index.php/featured-ingredients/testofen (last visited April 10, 2018).

136. As noted above, as support for their "proven" clinical results and general and specific product claims, Gencor Defendants rely on a Pilot Study, which is an exploratory study that does not support Defendants' bold, unqualified representations and promises.

137. Rather, an exploratory or pilot study, by its very nature, does not provide conclusive or even reliable results. Instead, a pilot study is a small-scale preliminary study conducted in order to evaluate feasibility, time, cost, adverse events, and statistical variability in an attempt to predict an appropriate sample size and improve upon study design prior to performing a full-scale research project or clinical study. See, e.g., Andrew C. Leon et al., The Role and Interpretation of Pilot Studies in Clinical Research, J. Psychiatr. Res. 45(5) at 626-29 (May 2011) ("A pilot study is not a hypothesis testing study. . . . [A] pilot study does not provide a meaningful effect size estimate for planning subsequent studies due to the imprecision inherent in data from small samples. Feasibility results do not necessarily generalize beyond the inclusion and exclusion criteria of the pilot design. . . . For purpose of contrast, a hypothesis testing clinical trial is designed to compare randomized treatment groups in order to draw an inference about efficacy/effectiveness and safety in the patient population, based on sample results."). In fact, however, such pilot studies cannot be the basis of formal proof of efficacy. Rather, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"), which issues "Good Clinical Practices" guidelines ("ICH GCP") 44 concludes that such exploratory studies/trials "cannot be the basis of

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<sup>&</sup>lt;sup>44</sup> The ICH GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human participants that has become the leading international guideline for the conduct of clinical trials.

the formal proof of efficacy, although they may contribute to the total body of relevant evidence."45

- 138. Regardless, Defendants manipulated the results of the Pilot Study to suggest statistical significance. A clinical protocol describes how a clinical trial will be conducted and ensures the safety of the trial subjects and integrity of the data collected.
- 139. The clinical protocol for the Pilot Study, titled "Effect of IND 6 on Muscular Strength, Endurance and Body Composition" is not publicly available and is in the sole possession of the Gencor Defendants.
- 140. The clinical protocol for the Pilot Study defines the "primary objectives" of the Pilot Study as (a) "To determine the effects of IND 6 [Testofen] on muscle strength and endurance during eight weeks of resistance exercise," and (b) "To evaluate safety of the test supplement."
- 141. Effect(s) of Testofen on testosterone levels is not a primary objective of the Pilot Study.
- 142. Rather, the protocol defines the "secondary objectives" of the Pilot Study: (a) "To determine the effects of the ingestion of IND 6 on muscle size during eight weeks of resistance exercise;" (b) "To determine the effects of ingestion of IND 6 on body composition during eight weeks of resistance exercise;" and (c) "To assess effect of IND 6 on serum testosterone (total and free) and prolactin levels."
- 143. The protocol provides that "Primary efficacy will be assessed on the basis of the following parameters" of "Muscular Strength and Endurance," which include: (a) "Change in 1-RM Bench Press;" (b) "Change in 1-RM Leg Extension;" (c) "Change in Bench Press repetitions

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<sup>&</sup>lt;sup>45</sup>http://www.ich.org/fileadmin/Public\_Web\_Site/ICH\_Products/Guidelines/Efficacy/E9/Step4/E9\_Guideline.pdf (last visited April 10, 2018).

at 80% of 1-RM at baseline;" and (d) "Change in Leg Extension repetitions at 80% of 1-RM at baseline."

- 144. The protocol states under "Clinical Efficacy Assessments" 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 Maxx, (ii) Change in Percent Body Fat, (iii) Change in Fat Mass, and (iv) Change in Body Weight." Testosterone (total or free) is not listed as a parameter.
- 145. Instead, the protocol states separately under "Laboratory Efficacy Assessments" that "Secondary efficiency will be assessed by measuring changes from baseline in serum testosterone (total and free) and prolactin levels after 8 weeks."
- 146. Thus, according to the protocol, the effect of Testofen on testosterone levels is not a primary objective of the Pilot Study; rather it is one of three secondary objectives. Further, the effect of Testofen on testosterone levels is not one of four primary outcome variables; rather it is one of many secondary outcome variables analyzed.
- 147. In human clinical trials for efficacy, statistical significance is attained when a p-value is less than the significance level. The level is traditionally at 5 percent. Hence, statistical significance is usually expressed as a standard alpha or "p<0.05." The greater the number of variables being analyzed from a single trial, the greater the likelihood of a false positive result, known as a "type I error," unless a corrective statistical technique is applied.
- 148. The ICH's Harmonised Tripartite Guideline, Statistical Principles for Clinical Trials, E9 (Feb. 4, 1998) (the "ICH Guideline") sets forth principals for the statistical analysis of

human clinical trials. Guidance promulgated by ICH has been adopted by regulatory bodies of the United States, European Union and Japan. *See* http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219488.htm (last visited Sept. 3, 2015).

149. Section 5.6 of the ICH Guideline states:<sup>46</sup>

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 .... In confirmatory analyses, any aspects of multiplicity which remain after steps of this kind have been taken should be identified in the protocol; adjustment should always be considered and the details or any adjustment procedure or an explanation of why adjustment is not thought to be necessary should be set out in the analysis plan.

- 150. Gencor Defendants made publicly available three versions of the Pilot Study on the "proven" effects of Testofen in increasing free testosterone levels: (1) Testofen Human Clinical Trial, Copyright 2006 by Gencor Pacific, Inc. (the "2006 Report"); (2) Testofen Human Clinical Study for Free Testosterone & Muscle Mass Boosting, Copyright 2008 by Gencor Nutrients (the "2008 Report"); and (3) Testofen Human Clinical Study for Free Testosterone & Muscle Mass Boosting, Copyright 2013 by Gencor Nutrients, Inc. (the "2013 Study"). The 2013 version is a duplicate of the 2008 Report.
- 151. The 2006 Report indicates that the trial is an exploratory study ("this trial is designed to explore ...") on the efficacy and safety of Testofen. It further states that the primary objective of the study is "to determine the effects of TESTOFEN on free testosterone and body composition."
- 152. However, the primary objective indicated in the 2006 Report is contrary to the protocol of the Pilot Study, which stated that the primary objective of the Pilot Study is to

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<sup>&</sup>lt;sup>46</sup>http://www.ich.org/fileadmin/Public\_Web\_Site/ICH\_Products/Guidelines/Efficacy/E9/Step4/E9\_Guideline.pdf (last visited April 10, 2018).

determine the effects of Testofen on muscle strength and endurance. The 2006 Report fails to mention that change in free testosterone levels is one of many secondary outcome variables analyzed.

153. The 2006 Report presents the following pretreatment and post-treatment levels of free testosterone. While the 2006 Report does not make a claim of statistical significance, it claims that "TESTOFEN has positive effects on the biologically active free testosterone secretion."

Results	Free testosterone pg/ml
Pretreatment levels	17.76
Post-treatment levels	35.29
Total Increase	17.55
% of Increase	98.81%

154. However, in the reported results, the investigators make no distinction between primary and secondary outcome measures or explanatory variables. Significantly, though, secondary variables/outcomes and analyses based upon them are performed for heuristic, exploratory purposes only and are not considered as evidence for the efficacy of a therapy. Data is collected and analyzed on secondary outcomes which are other areas of interest in the study but these outcomes are not accepted as evidence for or against the efficacy of a medical therapy. Rather they are explanatory in nature and often used to suggest further areas in need of exploration in future work. None of these secondary analyses would be considered as evidence for the efficacy of the Company's product by research bodies such as the FDA, the National Institute of Health ("NIH"), or a reputable peer-reviewed journal. Under normal protocol, a second Randomized Controlled Trial ("RCT") would need to be conducted in which these secondary outcomes would then need to be specified as primary endpoints and the entire trial repeated.

- 155. The 2008 Report identifies the primary "end point" as "To determine the effect of TESTOFEN® on safety, anabolic activity, blood testosterone, immune function during 8 weeks of intense resistance exercise" and stated that "blood testosterone both total and free" is one of three primary efficacy parameters.
- 156. The primary objective indicated in the 2008 Study is contrary to the protocol, which stated that the primary objective of the Pilot Study is to determine the effects of Testofen on muscle strength and endurance. The 2008 Report fails to mention that the change in free testosterone levels is one of many secondary outcome variables analyzed.
- 157. The 2008 Report presents the following results for free testosterone levels and concludes that "TESTOFEN group has significant increase in Free Testosterone (p<0.05) compared to Placebo."

Parameters	Testofen	Placebo	
Pre Treatment	17.76	21.30	
Post Treatment	35.29	31.70	
P value	0.0001	0.014	
Percentage change	96	48*	P Value < 0.5

outcome variable in the Pilot Study (as set forth in the protocol), but rather one of many secondary outcome variables, the threshold for statistical significance must be adjusted upward to reflect this multiplicity of comparisons under universally accepted principles of statistical analysis or so-called Type I error, the probability that a null hypothesis is rejected when the null hypothesis is actually true. The greater the number of statistical tests performed, the greater the probability that one or more of them will yield a statistically significant result by chance alone. One consequence of conducting multiple analyses is that it increases the likelihood of false positive results, making it possible for an investigator to choose the most favorable result from

among many analyses that have been performed. Regulatory agencies<sup>47</sup> and biostatisticians<sup>48</sup> and scientific journals often advocate the use of appropriate adjustments to control the overall probability of a Type I error when multiple endpoints are included in clinical trials. The Gencor Defendants did not do this or explain why any adjustments were unnecessary. Rather, appropriate adjustments would result in statistically insignificant P Value, rendering the efficacy claims made by Defendants false, misleading and deceptive.

- 159. Brand Defendants incorporated results for free testosterone levels from both the 2006 Report and 2008 Report in their marketing campaign to misstate the efficacy of the product and/or falsely represent the ability of Testofen to boost testosterone levels.
- 160. Moreover, the Testofen Products, however, do not do not affect—much less increase—free testosterone levels. Specifically, additional clinical studies on Fenugreek seed extract show no ability to boost testosterone levels or increase sex drive in the human male. In fact, a study titled *Fenugreek Extract Supplementation Has No effect on the Hormonal Profile of Resistance Trained Males* concluded that "supplementation of fenugreek extract does not appear to affect hormonal status in resistance trained males and shows no anabolic potential as has been purported."
- 161. Further, a human clinical trial that compared Testofen to placebo found that Testofen has no effect on testosterone levels.<sup>50</sup> This study, also cited to by Gencor to support its claim that Testofen promotes sexual desire and vitality, reported "Serum prolactin and"

<sup>&</sup>lt;sup>47</sup> U.S. Department of Health and Human Services. Guidance for industry: E9 statistical principles for clinical trials. Rockville, MD: Office of Training and Communication, Food and Drug Administration, 1998.

<sup>&</sup>lt;sup>48</sup> Bauer P, Chi G, Geller N, Gould AL, Jordan D, Mohanty S, et al. Industry, government, and academic panel discussion on multiple comparisons in a "real" phase three clinical trial. J Biopharm Stat 2003;13:691–701.

<sup>&</sup>lt;sup>49</sup> B. Brandon *et al.*, (2009) "Fenugreek Extract Supplementation Has No effect on the Hormonal Profile of Resistance-Trained Males," *International Journal of Exercise Science: Conference Proceedings*: Vol. 2: Iss. 1, Article 13, *available at* http://digitalcommons.wku.edu/ijesab/vol2/iss1/13

<sup>&</sup>lt;sup>50</sup> E. Steels, et al., (2011) Physiological Aspects of Male Libido Enhanced by Standardized Trigonella foenum-graecum Extract and Mineral Formulation, *Phytotheropy Res*.

Testofen did not raise testosterone levels. Moreover, according to the study, men who received the Testofen reported greater feelings of sexual arousal, orgasm, libido, well-being, energy and muscular strength, but no change in mood was reported. No explanation was given for the fact that the men in the study reported no change in mood, yet they reported better "well-being." Additionally, this study did not directly measure strength or energy levels; rather, the men just reported that they felt stronger and had more energy.

- 162. At least three other studies have similarly shown that fenugreek extract has no effect on free testosterone levels.
- 163. A 2009 study investigating the potential anabolic effects of fenugreek extract supplementation in conjunction with a controlled resistance training program observed no significant effects for groups or interactions for free testosterone.<sup>51</sup> Thus, the study concluded that fenugreek extract has no effect on free testosterone levels.
- 164. Another 2009 study found that "[s]upplementation of fenugreek extract resulted in a decrease in serum DHT levels in comparison to placebo. However, other anabolic and metabolic hormone analyses were not affected by supplementation." Accordingly, the authors "conclude that in conjunction with structured resistance training, supplementation of fenugreek extract does not appear to affect hormonal status in resistance trained males and shows no anabolic potential as has been purported." <sup>52</sup>
- 165. Similarly, a 2010 study evaluated the effects of Fenugreek supplementation on strength and body composition, and results demonstrated "no between or within group

<sup>52</sup> See, e.g., C. Poole, et al., (2009) Effects of TESTOSURGE supplementation on strength, body composition and hormonal profiles during an 8-week resistance training program, *Journal of International Society Sports Nutrition*.

<sup>&</sup>lt;sup>51</sup> 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.

differences were observed for any of the measured hormone variables, except for free testosterone." However, the authors pointed out that the between group difference "has limited relevance due to the fact that it did not change significantly over time." The authors concluded based on the results that "commercially available supplement lacks the potential for altering hormone values in combination with a resistance training regimen. <sup>53</sup>

166. In sum, Defendants rely on results from studies that, as demonstrated by Defendants' own descriptions cannot support the Testofen Products claims. Not surprisingly, therefore, the actual experiences of Plaintiffs using Testofen Products also demonstrate that these products do not deliver the results represented and/or promised by Defendants. Simply stated, Defendants' marketing campaign is false, misleading and deceptive and/or contain material omission.

167. By manufacturing, marketing and selling Testofen without the requisite competent and reliable scientific evidence and substantiation for its representations, Defendants have failed to comply with the clear standards set forth under DSHEA, and have violated the MMPA, California Unfair Competition and Advertising Laws and Massachusetts Consumer Protection Act (collectively "Consumer Protection Acts").

168. Likewise, Defendants' representations that Testofen increases, boosts, and/or supports free testosterone levels were part of the basis of the bargain under which Plaintiffs and Class Members purchased products containing Testofen, and were material factors in inducing Plaintiffs and the Class Members to purchase such products.

<sup>&</sup>lt;sup>53</sup> C. Poole *et al.*, (2010), The effects of commercially available botanical supplementation on strength, body composition, power output, and hormonal profiles in resistance-trained males, *Journal of International Society Sports Nutrition*.

- 169. Plaintiffs and Class Members have been and will continue to be deceived or misled by Defendants' representations that (1) the Product is clinically tested when it does not meet the basic industry standard for such testing and (2) that Testofen increases, boosts, and/or supports free testosterone levels. Plaintiffs and Class Members have been damaged in their purchases of supplements containing Testofen and have been deceived into purchasing products that they believed, based on Defendants' representations, increase, boost, and/or support free testosterone levels, when they did not.
- 170. Plaintiffs and the Class Members have been damaged in their purchases of supplements containing Testofen.
- 171. Defendants' representations regarding clinical testing and Testofen's ability to boost testosterone were part of the basis of the bargain under which Plaintiffs and Class Members purchased products containing Testofen, and were material factors in inducing Plaintiffs and the Class Members to purchase such products.
- 172. The GNC Defendants participated in, controlled, adopted and/or reinforced the false and misleading advertising claims about products containing Testofen, by among other things: (1) displaying Products and their false packaging claims on their store shelves; (2) utilizing false and misleading in-store Products advertisements, displays and/or exhibits; (3) displaying Products and their false packaging claims on the GNC branded website, including pictures of the false and deceptive packaging and the labeling of the Products on their websites; (4) making statements on their websites that repeated and reinforced the false and misleading statements contained on the packaging and labeling of the Products; (5) reviewing and approving false and misleading advertising materials for promoting the sale of Products, including

advertisements that bore the retailers' names, logos and/or trademarks; and (6) selling Products to end users in the United States including the State of Missouri and California.

#### DEFENDANTS' FALSE AND MISLEADING CLAIMS ARE MATERIAL

- 173. The representations at issue are ubiquitous. In commercial videos, in retail stores, on their respective internet websites, and on Defendants' websites, Defendants make the same representations about the Testofen Products—namely that the Products are an effective testosterone booster and that the claims were backed by clinical studies and/or research. Moreover, every package of the Products contain these representations.
- 174. All of Defendants' claims challenged herein relate to matters that are material and important to a consumer's purchasing decision, as they concern core claims about the Products which are likely to, and did, influence consumers' purchase of the Testofen Products.
- 175. Defendants' marketing, advertising, and packaging materials intended to, and did, induce Plaintiffs and Members of the Class to rely upon Defendants' representations that the Testofen Products were effective for their intended use and in the way described. These representations were a substantial factor in causing Plaintiffs and Members of the Class to purchase the Testofen Products instead of an effective testosterone booster.
- 176. At the time Plaintiffs and Members of the Class purchased the Testofen Products, they were unaware of the fact that: (1) Defendants' claims that the Testofen Products could boost testosterone levels are bogus; and (2) the Testofen Products are not proven effective for their intended use.
- 177. If Plaintiffs and Members of the Class had been aware of the true facts concerning the Testofen Products, Plaintiffs and Members of the Class would not have purchased the Products. Plaintiffs and Members of the Class have been injured in fact and have suffered out of

pocket losses. Plaintiffs and Members of the Class therefore seek a refund and/or rescission of the transaction and all further equitable and injunctive relief as provided by applicable law.

#### **CLASS ALLEGATIONS**

- 178. Pursuant to Missouri Rule of Civil Procedure 52.08, Plaintiffs bring this action on behalf of a Class of all other similarly situated persons who bought the Testofen Products on or after January 1, 2010.
- 179. Plaintiff Robbins also brings this action on behalf of a Missouri Subclass, defined as all other similarly situated persons who bought the Testofen Products or received a trial offer (class members who paid for shipping of a Trial Offer which were distributed by any of the Brand Defendants) on or after January 1, 2010.
- 180. Plaintiffs Camey and Alvandi also bring this action on behalf of a California Subclass, defined as all other similarly situated persons who bought the Testofen Products or received a trial offer (class members who paid for shipping of a Trial Offer which were distributed by any of the Brand Defendants) on or after January 1, 2010.
- 181. Plaintiff Butler also brings this action on behalf of a Massachusetts Subclass, defined as all other similarly situated persons who bought the Testofen Products or received a trial offer (class members who paid for shipping of a Trial Offer which were distributed by any of the Brand Defendants) on or after January 1, 2010.
- 182. Excluded from the Class and Subclasses are: (a) all Persons who purchased or acquired the Products for resale; (b) Defendants and their employees, principals, affiliated entities, legal representatives, successors and assigns; (c) any Person who files a valid, timely request to Opt-Out; (d) federal, state, and local governments (including all agencies and

subdivisions thereof, but excluding employees thereof); and (e) the judges to whom the Testofen Litigation is assigned and any member of their immediate family.

- 183. Upon information and belief, the Class and Subclasses consists of hundreds or thousands of purchasers. Accordingly, it would be impracticable to join all Class Members before the Court.
- 184. There are numerous and substantial questions of law or fact common to all of the members of the Class that predominate over any individual issues. Included within the common questions of law or fact are:
  - a. Whether Testofen increases, boosts or supports free testosterone levels;
  - b. Whether Defendants' claims regarding the benefits of Testofen are misleading, false and/or deceptive;
  - c. Whether Defendants' claims that they conducted clinical studies or trials related to Testofen are misleading, false and/or deceptive;
  - d. Whether the Testofen Study is unreliable and not competent;
  - e. Whether Defendants misrepresented the results of the Testofen Study;
  - f. Whether Defendants violated the MMPA;
  - g. Whether Defendants breached an express warranty with respect to the Testofen Products;
  - h. Whether Defendants breached an implied warranty with respect to the Testofen Products;
  - i. Whether Defendants violated the California Unfair Competition and Advertising laws;
  - j. Whether Defendants have been unjustly enriched by the sale of Testofen;

- k. Whether Plaintiffs and Class Members have sustained damages as a result of Defendants' unlawful conduct; and
- 1. The proper measure of damages sustained by Plaintiffs and Class Members.
- 185. Plaintiffs' claims are typical of the claims of Class Members, in that they share the above-referenced facts and legal claims or questions with Class Members, there is a sufficient relationship between the damage to Plaintiffs and Defendants' conduct affecting Class Members, and Plaintiffs have no interests adverse to the interests of other Class Members.
- 186. Plaintiffs will fairly and adequately protect the interests of Class Members and have retained counsel experienced and competent in the prosecution of complex class actions, including complex questions that arise in consumer protection litigation.
- 187. A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all Class Members is impracticable and no other group method of adjudication of all claims asserted herein is more efficient and manageable for at least the following reasons:
  - a. The claims presented in this case predominate over any questions of law or fact, if any exists at all, affecting any individual member of the Class;
  - Absent a Class, the Class Members will continue to suffer damage and Defendants' unlawful conduct will continue without remedy while Defendants profit from and enjoys their ill-gotten gains;
  - c. Given the size of individual Class Members' claims, few, if any, Class Members could afford to or would seek legal redress individually for the wrongs Defendants committed against them, and absent Class Members have

- no substantial interest in individually controlling the prosecution of individual actions;
- d. When the liability of Defendants have been adjudicated, claims of all Class
   Members can be administered efficiently and/or determined uniformly by the
   Court; and
- e. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiffs and members of the Class can seek redress for the harm caused to them by Defendants.
- 188. Because Plaintiffs seek relief for the entire Class, the prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual member of the Class, which would establish incompatible standards of conduct for Defendants.
- 189. Further, bringing individual claims would overburden the courts and be an inefficient method of resolving the dispute, which is the center of this litigation. Adjudications with respect to individual members of the Class would, as a practical matter, be dispositive of the interest of other members of the Class who are not parties to the adjudication and may impair or impede their ability to protect their interests. As a consequence, class treatment is a superior method for adjudication of the issues in this case.

# FIRST CLAIM FOR RELIEF VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT (RSMo § 407, et seq.) (By Plaintiff Robbins Against All Defendants)

94. Plaintiffs repeat and re-allege the allegations of the preceding paragraphs as if fully set forth herein.

- 95. Plaintiff Robbins brings this claim individually and on behalf of a Missouri Subclass for Defendants' violations of the "MMPA". The MMPA "is designed to regulate the marketplace to the advantage of those traditionally thought to have unequal bargaining power as well as those who may fall victim to unfair practices." *Huch v. Charter Commc'ns Inc.*, 290 S.W. 3d 721, 725 (Mo. banc. 2009). The MMPA provides that it is unlawful to "act, use or employ . . . deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce . . . . " *See* RSMo § 407.020.1.
- 96. The MMPA applies to both direct and indirect sellers, such as a manufacturer whose products are sold by a third party. *See Gibbons v. J. Nuckolls, Inc.*, 216 S.W.3d 667, 669 (Mo. banc. 2007) ("The statute's broad language of 'any person who has suffered any ascertainable loss' contemplates that other parties, besides the direct purchaser or contracting party, who suffer damages resulting from the violator's prohibited conduct under the Act are included among those eligible to receive restitution. The consumer who receives the product or services through a third party. . . is included within the meaning of the statute as one for whom restitution shall apply.").
- 97. Defendants' conduct as described above constitutes the act, use or employment of deception, fraud, false pretenses, false promises, misrepresentation, unfair practices and/or the concealment, suppression, or omission of any material facts in connection with the sale or advertisement of any merchandise in trade or commerce in that Defendants misrepresent that Testofen has been subjected to clinical trials or tests, and that Testofen increases, boosts, and/or supports free testosterone levels.

- 98. Plaintiff Robbins and Class Members purchased products containing Testofen for personal, family, or household purposes.
- 99. Plaintiff Robbins and Class Members suffered an ascertainable loss as a result of Defendants' unlawful conduct as alleged herein, including the difference between the actual value of the purchased products and the value of the product if the Testofen had been as represented. Had Plaintiff Robbins and Class Members known the truth about Testofen they would not have purchased products containing Testofen, or would have purchased the products on different terms. Plaintiff Robbins and Class Members thus purchased a a product worth less than what they paid for it.

#### SECOND CLAIM FOR RELIEF BREACH OF EXPRESS WARRANTY (By the Class Against All Defendants)

- 100. Plaintiffs and Class Members re-allege and incorporate by reference each allegation set forth above and further allege as follows.
- 101. Plaintiffs bring this claim individually and on behalf of the members of the Class against all Defendants.
- 102. In connection with the sale of the Products, Defendants expressly warranted by affirmation of fact or promise that the Products would boost testosterone levels, increase sex drive and libido, and are effective for the Products' intended use.
- 103. Defendants' express warranties as described herein were made part of the basis of the bargain when Plaintiffs and the Class Members purchased the Products.
- 104. The Products are not effective for their intended use and have never been proven effective by competent and reliable scientific evidence to dramatically boost testosterone levels.

- 105. Plaintiffs and Class Members were injured as a direct and proximate result of Defendants' breach because they would not have purchased the Products if the true facts had been known.
- 106. Defendants breached their express warranty by selling products that were not effective for their intended use and have never been proven effective by competent and reliable scientific evidence to boost testosterone levels.
- 107. More than thirty days prior to the filing of this action, Plaintiffs gave notice to Defendants that the warranties with respect to the Testofen Products had been breached, but Defendants failed and refused to take any steps to redress Plaintiffs' claims.

## THIRD CLAIM FOR RELIEF BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (By the Class Against All Defendants)

- 108. Plaintiffs and the Class Members re-allege and incorporate by reference each allegation set forth above and further allege as follows.
- 109. Plaintiffs bring this claim individually and on behalf of the members of the Class against all Defendants.
- 110. Defendants, as the designers, manufacturers, marketers, distributors, and sellers impliedly warranted that the Products were fit for their intended purpose in that the Products would function as effective testosterone boosters. Defendants did so with the intent to induce Plaintiffs and members of the Class to purchase the Products.
- 111. Defendants breached their implied warranties in the contract for the sale of the Products in that the Products are not, and do not contain ingredients, that will boost testosterone levels and therefore could not pass without objection in the trade under the contract description, the goods were not of fair average quality within the description, and the

goods were unfit for their intended and ordinary purpose because there is no competent and reliable scientific evidence that the Products possess testosterone boosting qualities. As a result, Plaintiffs and the Class Members did not receive the goods as impliedly warranted by Defendants to be merchantable.

- 112. In reliance upon Defendants' skill and judgment and the implied warranties discussed above, Plaintiffs and the Class Members purchased the Products for use as a testosterone booster, and to increase sex drive and libido, burn fat and build muscle.
- 113. The Products were not altered by Plaintiffs and the Class Members after purchase.
- 114. The Products were defective when they left the exclusive control of the Defendants.
- 115. Defendants knew the Products would be purchased and used without additional testing for efficacy by Plaintiffs and the Class Members.
- 116. The Products were defectively designed and unfit for their intended purpose, and Plaintiffs did not receive the goods as warranted. Had Plaintiffs and the members of the Class known the true facts, they would not have purchased the Products.
- 117. Plaintiffs and the Class Members were injured as a direct and proximate result of Defendants' breaches because they would not have purchased the Products if the true fact had been known.
- 118. More than thirty days prior to the filing of this action, Plaintiffs gave notice to Defendants that the implied warranties with respect to the Testofen Products had been breached, but Defendants failed and refused to take any steps to redress Plaintiffs' claims.

#### FOURTH CLAIM FOR RELIEF

#### UNJUST ENRICHMENT

(By the Class Against All Defendants)

- 119. Plaintiffs and Class Members re-allege and incorporate by reference each allegation set forth above and further allege as follows.
- 120. Plaintiffs bring this claim individually and on behalf of the members of the Class against all Defendants.
- 121. Defendants' practices described above resulted in Plaintiffs and the Class Members to purchase the Products.
- 122. By purchasing products containing Testofen, Plaintiffs and the Class Members conferred a benefit on Defendants.
- 123. The monies paid by Plaintiffs and the Class Members to Defendants conferred substantial benefits upon Defendants.
- 124. Defendants appreciated the benefit because, were consumers not to purchase products containing Testofen, Defendants would not generate revenue from the sale of Testofen.
- 125. Defendants knew of the benefits conferred upon them by Plaintiffs and the Class.
- 126. Defendants appreciated the benefits conferred upon it by Plaintiffs and the Class.
  - 127. Defendants accepted the benefits conferred upon it by Plaintiffs and the Class.
  - 128. Defendants retained the benefits conferred upon it by Plaintiffs and the Class.
- 129. Defendants' acceptance and retention of the benefit is inequitable and unjust because the benefit was obtained by Defendants' fraudulent and misleading representations

about Testofen.

- 130. By reason thereof, Defendants were unjustly enriched.
- 131. Plaintiffs and the Class have sustained damages.
- 132. Equity cannot in good conscience permit Defendants to be economically enriched for such actions at the Plaintiffs' and Class Members' expense and in violation of the law, and therefore restitution and/or disgorgement of such economic enrichment is required.

### FIFTH CLAIM FOR RELIEF VIOLATIONS OF CALIFORNIA'S UNFAIR COMPETITION LAW UNLAWFUL PRONG

(Cal. Bus. & Prof. Code § 17200 et seq.) (By Plaintiffs Camey and Alvandi Against All Defendants)

- 133. Plaintiffs and Class Members re-allege and incorporate by reference each allegation set forth above and further allege as follows.
- County California and conduct, engage in, and direct the unlawful, unfair and misleading business practices alleged herein targeting consumers nationwide. The State of California has a strong public interest to make sure that businesses operating within the State of California borders do not engage in unlawful, unfair and misleading business practices directed at consumers throughout the United States. At all relevant times alleged in this matter, each of the remaining Defendants acted in concert with, with the knowledge and approval of and/or as the agent of the Gencor Defendants within the course and scope of the agency, regarding the unlawful, unfair, and misleading business practices targeting consumers nationwide.
- 135. Plaintiffs Camey and Alvandi bring this claim individually and on behalf of the members of the California Subclass against all Defendants.

- 136. California Business and Professions Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."
- 137. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "unlawful" business acts and practices in that Defendants' conduct violates the False Advertising Law, and the Consumer Legal Remedies Act.
- 138. Defendants' conduct is further "unlawful" because it violates the FDCA and its implementing regulations in the following ways:
  - a. Defendants' deceptive statements violate 21 U.S.C. §§ 343(a) and 352, which deem a food or drug (including nutritional supplements) misbranded when the label contains a statement that is "false or misleading in any particular";
  - b. Defendants' deceptive statements violate 21 C.F.R. § 101.14(b)(3)(i), which mandates "substances" in dietary supplements consumed must contribute and retain "nutritive value," as defined under 21 C.F.R. § 101.14(a)(2)(3) when consumed at levels necessary to justify a claim;
  - c. Defendants' deceptive statements are *per se* false and misleading because the FDA has ruled there is a lack of adequate data to establish general recognition of the safety and effectiveness of any of the ingredients in the Products, or any other ingredient, for OTC use as an aphrodisiac; and labeling claims for aphrodisiacs for OTC use are "either false, misleading, or unsupported by scientific data." 21 C.F.R. § 310.528(a);
  - d. Defendants' deceptive statements violate 21 C.F.R. § 310.528(b), which mandates that any OTC product that is labeled, represented, or promoted for

use as an aphrodisiac, like the Products, are regarded as a "new drug" within the meaning of 21 U.S.C. § 355(p), but Defendants do not have new drug approval for the Products. Accordingly, the Products are misbranded under section 502(f)(1) of the FDCA; and

- e. Defendants' Products also violate the FDCA because, as an unapproved new drug and aphrodisiac, the Product cannot be generally recognized as safe and effective in the absence of a new drug application as set forth in the FDCA and its implementing regulations. 21 C.F.R. § 310.528(a).
- 139. Defendants' conduct is further "unlawful" because it violates the California Sherman Food, Drug, and Cosmetic Law, see Cal. Health & Safety Code § 109875-111900, which incorporates the provisions of the FDCA. See id. § 110110-110115.
- 140. In accordance with Bus. & Prof. Code § 17203, Plaintiffs seek an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices, and to commence a corrective advertising campaign.

## SIXTH CLAIM FOR RELIEF VIOLATIONS OF CALIFORNIA'S UNFAIR COMPETITION LAW UNFAIR AND FRAUDULENT PRONGS

(Cal. Bus. & Prof. Code § 17200 et seq.) (By Plaintiffs Camey and Alvandi Against All Defendants)

- 141. Plaintiffs and Class Members re-allege and incorporate by reference each allegation set forth above and further allege as follows.
- 142. The Gencor Defendants maintain their principal place of business in Orange County California and conduct, engage in, and direct the unlawful, unfair and misleading business practices alleged herein targeting consumers nationwide. The State of California has a strong public interest to make sure that businesses operating within the State of California

borders do not engage in unlawful, unfair and misleading business practices directed at consumers throughout the United States. At all relevant times alleged in this matter, each of the remaining Defendants acted in concert with, with the knowledge and approval of and/or as the agent of the Gencor Defendants within the course and scope of the agency, regarding the unlawful, unfair and misleading business practices targeting consumers nationwide.

- 143. Plaintiffs Camey and Alvandi bring this claim individually and on behalf of the members of the California Subclass against all Defendants.
- 144. California Business and Professions Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."
- 145. The acts, omissions, misrepresentations, practices, and non-disclosures of the Defendants as alleged herein also constitute "unfair" business acts and practices under the UCL in that Defendants' conduct is immoral, unscrupulous, and offends public policy by seeking to profit from male vulnerability to false or deceptive virility or aphrodisiac claims. Further, the gravity of Defendants' conduct outweighs any conceivable benefit of such conduct.
- 146. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants, as alleged herein, constitute "fraudulent" business acts and practices under the UCL in that Defendants' claims are false, misleading, and have a tendency to deceive the Class and the general public, as detailed herein.
- 147. In accordance with Bus. & Prof. Code § 17203, Plaintiffs seek an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices, and to commence a corrective advertising campaign.
  - 148. Plaintiffs further seek an order for the disgorgement and restitution of all

monies from the sale of the Defendants' Products, which were acquired through acts of unlawful, unfair, and/or fraudulent competition.

#### SEVENTH CLAIM FOR RELIEF VIOLATIONS OF CALIFORNIA'S FALSE ADVERTISING LAW (Cal. Bus. & Prof. Code § 17500 et seq.)

(By Plaintiffs Camey and Alvandi Against All Defendants)

- 149. Plaintiffs and the Class Members re-allege and incorporate by reference each allegation set forth above and further allege as follows.
- County California and conduct, engage in, and direct the unlawful, unfair and misleading business practices alleged herein targeting consumers nationwide. The State of California has a strong public interest to make sure that businesses operating within the State of California borders do not engage in unlawful, unfair and misleading business practices directed at consumers throughout the United States. At all relevant times alleged in this matter, each of the remaining Defendants acted in concert with, with the knowledge and approval of and/or as the agent of the Gencor Defendants within the course and scope of the agency, regarding the unlawful, unfair and misleading business practices targeting consumers nationwide.
- 151. Plaintiffs Camey and Alvandi bring this claim individually and on behalf of the members of the California Subclass against all Defendants.
- 152. Plaintiffs have standing to pursue this claim as each of them suffered injury in fact as a result of Defendants' actions as set forth herein. Specifically, Plaintiffs purchased one or more Products in reliance upon Defendants' marketing claims prior to the filing of this action. Plaintiffs used the products as directed, but did not know that the Products cannot work as advertised, nor provide any of the promised benefits.
  - 153. In violation of California Business and Professions Code § 17500 et seq., the

advertisements, labeling, policies, acts, and practices described herein were designed to, and did, result in the purchase and use of the Products.

- 154. Defendants knew, and reasonably should have known, that the labels on Defendants' Products were untrue and/or misleading.
- 155. Plaintiffs suffered lost money or property as a result of Defendants' False Advertising Law violations because they would not have purchased the Products if they knew the truth about the Products.
- 156. As a result, Plaintiffs, the Classes, and the general public are entitled to injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which Defendants were unjustly enriched.

# EIGHTH CLAIM FOR RELIEF VIOLATIONS OF CALIFORNIA'S CONSUMER LEGAL REMEDIES ACT (Cal. Civ. Code § 1750 et seq.) (By Plaintiffs Camey and Alvandi Against All Defendants)

- 157. Plaintiffs and the Class Members re-allege and incorporate by reference each allegation set forth above and further allege as follows.
- County California and conduct, engage in, and direct the unlawful, unfair and misleading business practices alleged herein targeting consumers nationwide. The State of California has a strong public interest to make sure that businesses operating within the State of California borders do not engage in unlawful, unfair and misleading business practices directed at consumers throughout the United States. At all relevant times alleged in this matter, each of the remaining Defendants acted in concert with, with the knowledge and approval of and/or as the agent of the Gencor Defendants within the course and scope of the agency, regarding the unlawful, unfair and misleading business practices targeting consumers nationwide.

- 159. Plaintiffs Camey and Alvandi bring this claim individually and on behalf of the members of the California Subclass against all Defendants.
- 160. The Consumer Legal Remedies Act ("CLRA") prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.
- 161. Defendants' false and misleading labeling and other policies, acts, and practices were designed to, and did, induce the purchase and use of Defendants' Products for personal, family, or household purposes by Plaintiffs and the Class Members, and violated and continue to violate the following sections of the CLRA:
  - a. § 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have;
  - b. § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another;
  - c. § 1770(a)(9): advertising goods with intent not to sell them as advertised;
     and
  - d. § 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.
- 162. As a result, Plaintiffs and the Class have suffered irreparable harm and seek injunctive relief under the CLRA.
- 163. Pursuant to section 1782 *et seq.* of the CLRA, Plaintiffs notified the Defendants in writing by certified mail of the particular violations of § 1770 of the Act as to the Products and demanded that Defendants rectify the problems associated with the actions detailed above and give notice to all affected consumers of their intent to so act.

Defendants' wrongful business practices regarding the Products constituted, and constitute, a continuing course of conduct in violation of the CLRA since Defendants still represent that the Products have characteristics, uses, benefits, and abilities which are false and misleading, and have injured Plaintiffs and the Class.

164. Because Defendants failed to implement remedial measures, Plaintiffs seek actual damages, punitive damages, and attorneys' fees and costs for Defendants' CLRA claims.

#### NINTH CLAIM FOR RELIEF

### BREACH OF CALIFORNIA'S SONG-BEVERLY CONSUMER WARRANTY ACT (Cal. Civ. Code § 1790 et seq.)

(By Plaintiffs Camey and Alvandi Against All Defendants)

- 165. Plaintiffs and the Class Members re-allege and incorporate by reference each allegation set forth above and further allege as follows.
- 166. Plaintiffs Camey and Alvandi bring this claim individually and on behalf of the members of the California Subclass against all Defendants.
- 167. The Products are consumer goods because they are for personal, family or household purposes, and were purchased at retail sale by Plaintiffs and the Class from Defendants. *See* Cal. Civ. Code §§ 1791, 1792.
- 168. The Products are intended for human consumption. See Klein v. Duchess Sandwich Co., 14 Cal. 2d 272, 276-84, 93 P.2d 799 (1939); Gottsdanker v. Cutter Labs., 182 Cal. App. 2d 602, 606-07, 6 Cal. Rptr. 320 (1960).
- 169. Defendants are merchants or retailers with respect to the goods sold. Cal. Civ. Code §§ 1792, 1791.1(a).
- 170. Defendants warrant that the Products will (i) boost testosterone levels, (ii) boost sex drive and libido, and (iii) are effective for the Products' intended use.

- 171. The warranty was breached because the Products are not reasonably fit for the ordinary purposes for which such goods are used, or the Products did not reasonably conform to the promises or affirmations of fact on the container or label. CACI 1230, 1231, 1232, 1233; see also Cal. Civ. Code §§ 1792, 1791.1(a).
- 172. Defendants' breach of warranty caused Plaintiffs and the Class to suffer damage in the amount of the total purchase of the Products.
- 173. In addition to compensatory damages, Cal. Civ. Code § 1794, Plaintiffs and the Class are entitled to rescission, *id.* § 1794(b)(1), costs, attorneys' fees and statutory penalties, *id.* § 1794(c).

## TENTH CLAIM FOR RELIEF VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT (Mass. Gen. Laws ch. 93A) (By Plaintiff Butler Against Defendant Direct Digital, LLC)

- 174. Plaintiffs and the Class Members re-allege and incorporate by reference each allegation set forth above and further allege as follows.
- 175. Plaintiff Butler brings this claim individually and on behalf of the members of the Massachusetts Subclass against Defendant Direct Digital, LLC.
  - 176. Plaintiff Butler and the Massachusetts subclass are persons.
  - 177. Defendant Direct Digital, LLC was engaged in trade or commerce.
- 178. Plaintiff Butler and the Class entered into consumer transactions with Defendant Direct Digital, LLC.
- 179. Defendant Direct Digital, LLC engaged in unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices, in the conduct of trade or commerce.

180. Defendant Direct Digital, LLC's acts and conduct were willful and knowing violations and invaded the rights of Plaintiffs and the Class to be free from deceptive business practices.

181. More than thirty days prior to filing the initial Complaint, Plaintiff Butler made a written demand for relief from Defendant Direct Digital, LLC.

182. As a proximate and foreseeable consequence of Defendant Direct Digital, LLC's violations, Plaintiff and the Class sustained damages.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all similarly situated persons, pray the Court:

- A. Grants certification of this case as a class action;
- B. Appoint Plaintiffs as Class Representatives and Plaintiffs' counsel as Class Counsel:
  - C. Award compensatory damages to Plaintiffs and the proposed Class;
  - D. Award reasonable and necessary attorneys' fees and costs to Class counsel; and
  - E. For all such other and further relief as may be just and proper.

Dated this 14<sup>th</sup> day of May, 2018.

Tommy Robbins, Daniel Camey, Raymond Alvandi, and Gerard Butler, Individually, and on Behalf of a Class of Similarly Situated Individuals, Plaintiffs

By: /s/ Stephen F. Gaunt

Stephen F. Gaunt, #33183 sgaunt@steelmanandgaunt.com David L. Steelman, #27334 dsteelman@steelmanandgaunt.com STEELMAN, GAUNT & HORSEFIELD 901 Pine Street, Suite 110 Rolla, Missouri 65401 Tel: (573) 458-5231 Fax: (573) 341-8548

Ronald A. Marron ron@consumersadvocates.com Law Offices of Ronald A. Marron, APLC 651 Arroyo Drive San Diego, California 92103

Tel: (619) 696-9006 Fax: (619) 564-6665

Antonio Vozzolo avozzolo@vozzolo.com Vozzolo LLC 345 Route 17 South Upper Saddle River, New Jersey 07458

Tel: (201) 630-8820 Fax: (201) 604-8400

Attorneys for Plaintiffs and the Putative Class