UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14cv1748 Honorable Matthew F. Kennelly
MEDICAL MUTUAL OF OHIO, Plaintiff, v. ABBVIE INC., ABBOTT LABORATORIES, ABBOTT PRODUCTS, INC., SOLVAY AMERICA, INC., SOLVAY NORTH AMERICA, LLC, SOLVAY PHARMACEUTICALS, INC., SOLVAY PHARMACEUTICALS SARL, SOLVAY S.A., AUXILIUM, INC., ELI LILLY AND COMPANY, LILLY USA, INC., ACRUX LIMITED, ACTAVIS PLC, ACTAVIS, INC., ACTAVIS PHARMA, INC., WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ANDA, INC., and ENDO PHARMACEUTICALS, INC., Defendants.	**No.** 1:14-cv-8857 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

TABLE OF CONTENTS

Page

I. NATURE OF THE CASE 1
II. PARTIES 12
III. JURISDICTION AND VENUE 20
IV. FACTUAL ALLEGATIONS: TRT DRUGS' BACKGROUND....21
V. FORMATION OF THE UNLAWFUL TRT DRUGS MARKETING ENTERPRISES 25
A. Formation of the Illegal Peer Selling Enterprises 28
a. Role of Medical Marketing Firms in Peer Selling Enterprises 31
b. Role of Physicians in the Peer Selling Enterprises 36
B. Formation of the Illegal Publication Enterprises 45
C. Formation of the Illegal DTC Enterprises 50
VI. THE ABBVIE DEFENDANTS' FRAUDULENT MARKETING OF ANDROGEL....57
A. The AndroGel Peer Selling Enterprise 58
a. CME Events....63
b. Promotional Speakers 65
c. AndroGel Peer Selling Message to Physicians....67
d. Marketing AndroGel from the Outset for the Treatment of "Andropause"....68
e. Other Andropause-Related Off-Label Uses: Depression; Osteoporosis; and Sexual Dysfunction 76
f. Off-Label Promotion of AndroGel to Women....80
g. Off-Label Promotion of AndroGel to Target Patient Populations....82
i. Off-Label Promotion for the Treatment of Diabetes 83
ii. Off-Label Promotion for the Treatment of Obesity....84
iii. Off-Label Promotion for the Treatment of Pain 85
iv. Off-Label Promotion for the Treatment of HIV/AIDS....85
h. The AbbVie Defendants' Widespread Use of Kickbacks to Induce Prescribing 86
i. Cash-for-Prescriptions to Induce Off-Label Prescribing of AndroGel....87
ii. Speaker Honoraria to Induce Off-Label Prescribing of AndroGel....88

iii. Speaker Training Workshops....89
iv. AndroGel Marketing Feedback Panels....90
v. District or Regional Advisory Boards....90
vi. Dinner Meetings with Speakers and Other Speaker Events to Induce AndroGel Off-Label Prescribing....91
vii. Regional "CAST" Programs to Drive Off-Label AndroGel Message....92
viii. Preceptorships to Induce AndroGel Off-Label Prescribing....93
ix. Honoraria and Grants for Bogus Clinical Trials, Studies and Focus Panels to Induce Off-Label Prescribing of AndroGel....94
x. Non-Cash Kickback Schemes to Induce Off-Label Prescribing of AndroGel....96
xi. Gifts to Induce Off-Label Prescribing of AndroGel....99

B. The AndroGel Publication Enterprise....101
C. The AndroGel DTC Enterprise....111

VII. AUXILIUM FRAUDULENT MARKETING OF TESTIM AND TESTOPEL....113

A. Auxilium's Testim and Testopel Peer Selling Enterprise....113
a. Testim Peer Selling Association with GSK....113
b. Testim Peer Selling Enterprise Association with Lathian Health....114
B. Auxilium's Testim and Testopel Publication Enterprise....116
C. The Testim and Testopel DTC Enterprise....119
a. The Testim DTC Enterprise Association with Heartbeat Ideas....119
b. The Testim and Testopel DTC Enterprise Association with Transit Creative Brand Design Group....122
c. The Testim DTC Enterprise Association with "e-tractions"....127
d. The Testopel DTC and Peer Selling Enterprise with TRG Communications, LLC....129

VIII. DEFENDANT ELI LILLY'S FRAUDULENT MARKETING OF AXIRON....130

A. The Axiron Peer Selling Enterprise....131
B. The Axiron Publication Enterprise....139
C. The Axiron DTC Enterprise....143

IX. DEFENDANT ACTAVIS' FRAUDULENT MARKETING OF ANDRODERM....147

A. The Androderm Peer Selling Enterprise....148
B. The Androderm Publication Enterprise....150

C. The Androderm DTC Enterprise 153
X. DEFENDANT ENDO'S FRAUDULENT MARKETING OF FORTESTA 155
A. The Fortesta Peer Selling Enterprise 156
B. The Fortesta Publication Enterprise 161
C. The Fortesta DTC Enterprise 166
XI. DEFENDANTS' TARGETING OF TPPS 169
A. TPP Drug Management Programs 169
B. TRT Drugs Have Been Widely Accepted as Preferred Drugs on TPP Formularies 174
C. Defendants Deceived TPPs into Placing TRT Drugs in Preferred Formulary Status So that They Could Undertake Their Fraudulent Promotion 179
D. Aggressive TPP Contracting to Ensure Favorable Formulary Placement 185
E. Defendants Used Favorable Formulary Status to "Pull Through" TRT Drug Prescriptions 187
XII. USE OF TRT DRUGS IS TIED TO SERIOUS CARDIOVASCULAR ADVERSE EVENTS 190
XIII. DEFENDANTS' CONCEALMENT OF THEIR FRAUDULENT CONDUCT 197
A. Defendants' Concealment of Serious Side Effects and Negative Safety Profiles 201
B. Injury to the Plaintiff and the Class Members: Defendants' Respective Schemes Caused Plaintiff and the Class to Pay for TRT Prescriptions Instead of More Appropriate, Cheaper Alternatives 201
C. Defendants' Use of the Mails and Wires to Create and Manage Their Fraudulent Scheme 203
XIV. CLASS ACTION ALLEGATIONS 204
XV. CLAIMS FOR RELIEF 209
FIRST CLAIM FOR RELIEF 209
SECOND CLAIM FOR RELIEF 213
THIRD CLAIM FOR RELIEF 218
FOURTH CLAIM FOR RELIEF 222
FIFTH CLAIM FOR RELIEF 227
SIXTH CLAIM FOR RELIEF 231
SEVENTH CLAIM FOR RELIEF 236
EIGHTH CLAIM FOR RELIEF 241

NINTH CLAIM FOR RELIEF 245
TENTH CLAIM FOR RELIEF 250
ELEVENTH CLAIM FOR RELIEF 255
TWELFTH CLAIM FOR RELIEF 259
THIRTEENTH CLAIM FOR RELIEF 264
FOURTEENTH CLAIM FOR RELIEF 268
FIFTEENTH CLAIM FOR RELIEF 272
SIXTEENTH CLAIM FOR RELIEF 276
SEVENTEENTH CLAIM FOR RELIEF 279
EIGHTEENTH CLAIM FOR RELIEF 282
NINETEENTH CLAIM FOR RELIEF 285
TWENTIETH CLAIM FOR RELIEF 288
TWENTY-FIRST CLAIM FOR RELIEF 291
TWENTY-SECOND CLAIM FOR RELIEF 293
TWENTY-THIRD CLAIM FOR RELIEF 298
TWENTY-FOURTH CLAIM FOR RELIEF 299
TWENTY-FIFTH CLAIM FOR RELIEF 300
TWENTY-SIXTH CLAIM FOR RELIEF 305
TWENTY-SEVENTH CLAIM FOR RELIEF 306
TWENTY-EIGHTH CLAIM FOR RELIEF 308
TWENTY-NINTH CLAIM FOR RELIEF 312
THIRTIETH CLAIM FOR RELIEF 314
THIRTY-FIRST CLAIM FOR RELIEF 319
THIRTY-SECOND CLAIM FOR RELIEF 320
THIRTY-THIRD CLAIM FOR RELIEF 321
THIRTY-FOURTH CLAIM FOR RELIEF 326
THIRTY-FIFTH CLAIM FOR RELIEF 327
THIRTY-SIXTH CLAIM FOR RELIEF 329
THIRTY-SEVENTH CLAIM FOR RELIEF 330
THIRTY-EIGHTH CAUSE OF ACTION 332
XVI. DEMAND FOR RELIEF 334

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Medical Mutual of Ohio ("MMO"), on behalf of itself and a class of similarly situated third party payors ("TPPs"), brings this lawsuit against Defendants AbbVie Inc., Abbott Laboratories, Abbott Products, Inc., Solvay America, Inc., Solvay North America, LLC, Solvay Pharmaceuticals, Inc., Solvay Pharmaceuticals Sarl, Solvay S.A., Auxilium, Inc., Eli Lilly and Company, Lilly USA, Inc., Acrux Limited, Actavis PLC, Actavis, Inc., Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Anda, Inc., and Endo Pharmaceuticals, Inc., alleging civil violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, violations of state consumer fraud and deceptive trade practices laws, negligent misrepresentation, common law fraud and unjust enrichment and equitable relief. The facts and information averred herein are based upon Plaintiff'ss personal knowledge and beliefs and upon investigation of counsel. Plaintiff allege as follows:

I. NATURE OF THE CASE

1. This case is brought by Plaintiff MMO on behalf of itself and TPP Class Members who paid all or a portion of the cost of AndroGel® (hereinafter "AndroGel"), Testim® ("Testim"), Testopel® ("Testopel"), Axiron® ("Axiron"), Androderm® ("Androderm"), and/or Fortesta Gel® ("Fortesta"), all of which are testosterone replacement therapy drugs (hereinafter "TRT drugs") marketed by the AbbVie Defendants (and their predecessors-in-interest) (hereinafter "the AbbVie Defendants"), Defendant Auxilium, Defendants Eli Lilly and Acrux (hereinafter "Defendant Lilly"), Defendants Actavis, Watson, and Anda (hereinafter "Defendant Actavis") and Defendant Endo, respectively.

2. These TRT drugs were marketed as part of a decade-long deceptive marketing scheme to transform the male aging process into a curable disease state Defendants variously

called "Andropause," "late-onset male hypogonadism," "age-related hypogonadism," or simply "Low T," which were invented from whole cloth; Defendants then promoted and marketed the TRT drugs to TPPs, patients, and physicians for "Andropause" and as a treatment for a host of medical problems, uses of which were not approved by the U.S. Food and Drug Administration ("FDA"), nor effective for such uses, so-called "off-label" uses, as described *infra*. As a direct result of Defendants' respective fraudulent marketing schemes, TPPs were financially injured by paying for TRT drugs that, unbeknownst to TPPs until recently, did not work as had been advertised and promoted.

3. Not only has it been recently established that the TRT drugs are ineffective for the vast majority of patients prescribed the drugs, unbeknownst to TPPs until recently, Defendants concealed serious side effects, including heart attacks, and other adverse events that Defendants knew or should have known were associated with TRT drug use.

4. Defendants' respective schemes concealed the fact that the vast majority of TRT patients did not and do not suffer from diagnosed hypogonadism, the only condition for which TRT drugs are indicated for treatment by the FDA. Defendants' respective but complementary marketing strategies specifically targeted for off-label TRT drug use patients with age-appropriate testosterone levels and patients with erectile dysfunction, diabetes, depression and obesity (among other off-label promotions), many of whom were already at higher risk for cardiovascular adverse events. Defendants succeeded in polluting the medical discourse and medical literature concerning testosterone therapy to such a degree that the contours of the entire disease state and diagnosis were blurred. In addition, Defendants ensured that Plaintiff and Class Member TPPs were kept in the dark about concerning off-label usage of TRT drugs

5. TRT did not begin with the approval of any of the TRT drugs referenced herein. In fact, isolated testosterone was first synthesized in 1935, and was introduced to the market shortly thereafter to treat hypogonadism. Thus, for example, TRT had been available for sixty-five (65) years when AndroGel came to the market.

6. In those sixty-five (65) years, TRT was appropriately limited to only those patients suffering from a rare condition called hypogonadism, with limited utilization data to match the disease state prevalence. In 1988, sales for drugs indicated to treat hypogonadism were approximately $18 million *in toto*. In 1997, approximately 806,000 TRT drug prescriptions were written. *See* Gina Kolata, *Male Hormone Therapy Popular But Untested*, New York Times, August 19, 2002, http://www.nytimes.com/2002/08/19/health /19HORM.html (last checked on September 22, 2014).

7. Coinciding with the approval of AndroGel in early 2000, and in the preceding and following years, Defendants' respective unlawful marketing schemes spawned voluminous medical literature. This literature was sponsored by each Defendant, and much of it focused on the prevalence of hypogonadism. What was once a rare condition was suddenly said to affect up to 40% of middle-aged men, according to respected "thought leaders" – specialist urologists and endrocrinologists at teaching university hospitals – many of whom were in fact on one or more of Defendants' respective payrolls as consultants, speakers, and/or researchers. Such studies were and are cited and re-cited *ad nauseam* by all TRT Defendants to create the impression that hypogonadism was a vastly underdiagnosed and prevalent condition. In this way, Defendants hoped and hope to disguise the rampant off-label prescribing of TRT drugs that resulted from their respective fraudulent promotional schemes; Defendants hoped and hope to pass their

fraudulent promotion off as simply an evolution in medicine resulting in increased on-label diagnoses.

8. These "thought leaders" were paid by Defendants to create the false impression among patients, physicians and TPPs (and the entire medical community) that almost half of the middle-aged male population in the world was hypogonadal and now needed TRT drugs. Just how rapidly and cooperatively Defendants worked to inflate the hypogonadism prevalence numbers (a form of off-label marketing referred to as "label expansion") is exemplified by two Solvay press releases less than a year apart. In the first, a Solvay press release dated March 2004, it was estimated that "four to five million American men are estimated to suffer from low testosterone," which was already grossly exaggerated, as discussed *infra*. In the second press release less than a year later, Solvay asserted (relying on a yet-to-be-published Solvay-funded study by a doctor on Solvay's payroll that was secretly ghostwritten by Solvay) that "[i]t is estimated that low T affects up to 13 million American men aged 45 and older …."

9. Auxilium's marketing campaign, relying on the Solvay HIM Study, likewise asserted that "[u]p to 13 million men in the United States may have low testosterone, although many don't know they are affected." Defendant Eli Lilly made similar statements in reliance on the HIM Study; upon Axiron's approval by the FDA, Lilly announced in a press release that "up to 13 million men over 45 years of age in the U.S. may have symptoms associated with low testosterone." Lilly also suggested that "up to 39% of men over 45 years of age may have testosterone levels below the normal healthy range." Auxilium then upped the ante by suggesting that "22.7 million men in this age group [50-64 year old men] suffer from low testosterone[.]" Aside from the inflation of the number of hypogonadal men increasing almost three-fold in less than a year according to Solvay and almost five-fold according to Auxilium, numerous articles

soon followed relating additional benefits to using TRT drugs. Most prominent among these benefits was the assertion that TRT drugs had the potential to reverse or slow the male aging process.

10. Defendants' respective unlawful marketing schemes directly convinced patients, physicians, and TPPs that hypogonadism was vastly underdiagnosed and undertreated, directly causing prescriptions for TRT drugs to increase 170% from 1999 to 2002. Sales of AndroGel alone amounted to $115.8 million (compared to only $26 million in 2000), and then skyrocketed thereafter. Plaintiff and Class Member TPPs at no point were aware that this increase was almost entirely attributable to ineffective, unsafe, and/or non-useful off-label utilization.

11. This dramatic increase in TRT prescribing has continued through the present. In the five (5) years leading up to 2012, according to IMS Health, sales of TRT drugs grew by 90%. In its 2011 Annual Report, Defendant Abbott identified "several key initiatives" for 2012, including "maximizing the market potential" for AndroGel. The initiative was apparently successful. By 2012, sales of AndroGel alone had topped $1 billion in the United States ($1.15 billion, an increase of nearly $250 million from $874 million in sales in 2011 according to AbbVie's 2013 Form 10-K), and sales of TRT drugs collectively had grown to about $2 billion annually. Testim's sales have increased to over $209 million per year, from $125 million in 2008. In 2011, Testim revenues accounted for nearly 80% of Defendant Auxilium's total net revenues.

12. The astronomical spike in prescriptions coincided with a proportionate increase in marketing money spent by the TRT Defendants and other TRT manufacturers. A Time Magazine cover article published August 18, 2014 regarding testosterone replacement therapy emphasized "that the low-T bandwagon will keep collecting passengers, fueled by a 2,800% increase in

marketing dollars[.]" Defendant Auxilium concurred in its Form 10-K for 2013: "We believe that the increase in promotional activities has been the primary driver of the growth of the overall TRT … market[ ]." Even one of the physician participants in the AbbVie Defendants' Peer Selling Enterprise, Dr. Natan Bar-Chama (a urologist who first gained notoriety when, as a speaker for Pfizer, he suggested "preventative" daily treatment with Viagra), remarked with astonishment how successful Defendants were in expanding the testosterone market: "All of a sudden you've got these big players with a lot of money using consumer directed marketing to change the landscape ... They see the potential, they see the market growth annually and it's very impressive."

13. According to one market research company, Encuity Research, "in 2009, the top six branded [TRT] products spent approximately $55 million on promotion, but by 2013 that number had grown five-fold to just over $282 million." Defendant Lilly's aggressive promotional efforts, after Axiron's approval in 2011, accounted for much of the increase; Defendant Lilly spent $122 million in 2013 alone promoting Axiron.

14. Sales of TRT drugs are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts.

15. While the efficacy of testosterone has long been an open question for non-hypogonadal men, many experts now believe TRT drugs are of negligible value for the marketed off-label uses. According to Dr. Brad Anawalt of the University of Washington, millions of patients are using TRT drugs off-label and with absolutely zero benefit: "For people with truly low testosterone levels, the benefits outweigh the risks … But for millions of others, it's in the same category as snake oil." *See* Roni Caryn Rabin, *Weighing Testosterone's Benefits And Risks*, New York Times, February 3, 2014, http://well.blogs.nytimes.com/2014/02/03/weighing-

testosterone-benefits-and-risks/ (last checked on September 22, 2014). Very recently, the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee voted 20-1 to limit testosterone prescribing, essentially rejecting the label-expanding efforts of Defendants.

16. As observed by Lisa M. Schwartz, M.D., M.S., and Steven Woloshin, M.D., M.S., in their article *Low T as a Template: How to Sell Disease* published in 173 JAMA Internal Medicine 1460-1462 (August 2013):

> Whether the campaign is motivated by a sincere desire to help men or simply by greed, we should recognize it for what it is: a mass, uncontrolled experiment that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels.
>
> . . . [T]here is a strong analogy between the marketing of testosterone therapy for men and estrogen therapy for menopausal women. Ignoring the lessons of estrogen therapy is scandalous. Before anyone makes millions of men aware of Low T, they should be required to do a large-scale randomized trial to demonstrate that testosterone therapy for healthy aging men does more good than harm.

17. TRT drug makers, including the Defendants and led initially by the AbbVie Defendants, created a disease state targeted specifically at aging men with age-appropriate or borderline testosterone levels that they labeled "Andropause" (the male version of menopause). It has been well known since the 1960's that, after reaching the age of thirty (30), men's testosterone levels can be expected to decline naturally by about 1% per year. However, according to the New York Times, "[t]o the pharmaceutical industry, that [natural] decline was ripe for treatment." *See* Natasha Singer, *Selling that New Man Feeling*, New York Times, November 23, 2013, http://www.nytimes.com/2013/11/24/business/selling-that-new-man-feeling.html?pagewanted=all (last checked on September 22, 2014).

18. With their respective schemes now exposed, estimates are that the vast majority of TRT drug use is for ineffective, unsafe, and/or unuseful off-label purposes. For once-daily TRT drugs, estimates are that such off-label use is even higher.

19. A study published in the Journal of the American Medical Association ("JAMA") in August 2013 indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had only a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription. *See* Baillargeon, J., et al., *Trends in Androgen Prescribing in the United States, 2001 to 2011*, 173 JAMA 12/26 (August 2013), http://archinte.jama network.comarticle.aspx?articleid=1691925 (last checked on September 22, 2014).

20. TRT drugs have not been proven to be safe or effective to treat male aging (no drug manufacturer has discovered or gained FDA approval for Ponce de León's fountain of youth). The same is true for the host of other symptoms and conditions for which Defendants promoted TRT drugs mostly as an "add-on" therapy (i.e., in conjunction with as opposed to replacing other on-label treatments). As explained by a vigorous promoter of testosterone therapy – Dr. Abraham Morgentaler (who has been paid many thousands of dollars by pharmaceutical companies with testosterone products on the market) – it can take "years, even decades, to correct a medical myth." Of course, Dr. Morgentaler was speaking of the association of testosterone and prostate cancer; however, his statement is more applicable to the marketing juggernaut Defendants have created surrounding testosterone therapy and male aging, which is only just beginning to be unraveled. This, combined with the recently revealed serious safety risks posed by TRT drugs, has resulted in a recent understanding that the vast majority of patients being prescribed TRT drugs should not have been using any TRT drug at all.

21. Moreover, Defendants knew of and concealed the serious adverse health effects associated with the off-label use of TRT drugs. Recent studies have demonstrated increased incidence of cardiovascular adverse events, including myocardial infarction, stroke, pulmonary embolism, and other thromboembolic adverse events. Aging men, the primary patient target for Defendants' label-expanding and off-label marketing scheme, tend to be at particular risk for such adverse events. In some patient populations, there is up to a 500% increased risk of such adverse events. As part of Defendants' illegal schemes to increase sales of their TRT drug(s), these known safety risks were and continue to be systematically concealed and minimized from the public and from TPPs.

22. For example, none of the seven (7) clinical trials referenced on the AndroGel Defendants' www.AndroGel.com website from 2000-2011 includes any meaningful reference to cardiovascular effects of AndroGel use. The same is true for Auxilium's www.testim.com website, as well as the websites of Defendant Lilly, Defendant Actavis, and Defendant Endo for Axiron, Androderm, and Fortesta, respectively. This is despite reports that several TRT drug makers have been proactively addressing cardiovascular safety issues in their promotional efforts. One physician who was detailed by Eli Lilly on Axiron noted that "[c]ardiovascular risk has all of a sudden become a discussion topic" in such details. Similarly, a physician detailed by the AbbVie Defendants on AndroGel noted that the sales rep was "[t]rying to quell concerns over cardiac risk." Until a Testim placebo-controlled study was halted in late 2009 due to cardiovascular adverse events in the Testim study group, Defendants ensured that the only cardiovascular health discussion relating to TRT drugs centered on potential (but quite obviously, unproven) cardio-protective effects. Even after the unusual halting of the Testim study, Defendants continued and continue to proclaim the safety of TRT therapy.

23. From 2000 until today, each Defendant has been engaged in a fraudulent and illegal scheme to cause increased prescribing and reimbursement for their drug TRT product(s). As the entities directly reimbursing most, if not all, of the cost of TRT Drug prescriptions, Plaintiff and Class Members were the primary and intended victims of these fraudulent schemes. Defendants' respective schemes targeted and defrauded TPPs on a massive scale. Defendants' respective fraudulent practices convinced patients they could benefit from TRT drug use, caused doctors to write prescriptions for TRT drugs that they otherwise would not have written, and caused TPPs to reimburse claims for prescriptions of each Defendant's drug product that they otherwise would not have paid.

24. Each Defendant knew that TPPs would reimburse for on-formulary prescriptions of TRT drugs, even if the drugs were being prescribed as a result of their respective covert systematic and illegal schemes to promote their TRT drug(s) for label-expanding or off-label uses. Although TPPs have a variety of tools that can be used to manage drug costs and promote high quality prescribing and utilization of pharmaceuticals, each Defendant knew that TPPs do not have the capability either to detect whether TRT drug prescriptions were written for off-label indications.

25. Consequently, TPPs included many of the TRT drugs on their formularies with few, if any, limitations, and unknowingly paid for TRT drug prescriptions for ineffective, unsafe, and/or non-useful off-label purposes as a result of Defendants' unlawful marketing practices. At all times material hereto, each Defendant knew that, because TRT drugs are FDA approved and effective for the treatment of the limited population of patients with hypogonadism, the products were placed without restrictions on most TPP formularies nationally.

26. Each Defendant knew that TPPs and their PBMs would be unable to identify off-label uses of TRT drugs from the pharmacy claim transactions they receive, or to easily be able to restrict utilization to on-label uses. This is because the diagnosis for which a drug is prescribed is not required on a prescription claim submitted to TPPs. Likewise, pharmacies do not have access to diagnostic information at the time a claim is processed for payment to TPPs. As a result, a diagnosis code is not included as a component of typical claim transactions and the diagnosis is unknown to TPPs and/or their PBMs. And even in situations where TPPs did request diagnostic information (such as, for example, by requiring prior authorization or a letter of medical necessity, discussed *infra*), each Defendant's sales force actively provided such forms and instructed doctors to disguise the fact that the TRT drug prescriptions were for off-label use.

27. At all times material hereto, each of the Defendants was well aware of the limitations faced by TPPs and PBMs in their ability to control off-label coverage of TRT drugs. As a result of Defendants' misrepresentation and concealment of the true safety and efficacy profiles of TRT drugs, Plaintiff and the Class Members were denied the opportunity to make fully informed decisions about whether and how to include TRT drugs on their formularies and/or paid for far more TRT drug prescriptions than they otherwise would have paid absent Defendants' fraudulent and illegal TRT drug promotion schemes. Plaintiff and the Class Members have been injured to the extent that they have paid for inappropriate use of TRT drugs and to the extent that Plaintiff and the Class Members have paid or will pay for the health care services and facilities resulting from adverse events associated with TRT drug use.

28. Due to Defendants' illegal marketing schemes and enterprises set forth in detail below, there resulted a flurry of fraudulent prescribing activity, which continues to this day. Plaintiff and the Class Members, as a direct and natural result of each Defendant's fraudulent

scheme, have been forced and will continue to be forced to reimburse millions of TRT drug prescriptions even though it has recently become apparent that, for the vast majority of TRT drug patients, no prescriptions should have or would have been written absent Defendants' unfair conduct and illegal enterprises.

29. In addition to the personal injuries, deaths, and other adverse events associated with TRT drug use, which have had serious implications for men's health, the financial impact of each Defendant's false and deceptive marketing of their respective TRT drug(s) has likewise been profound, especially for TPPs, which bear the ultimate cost of TRT drug prescriptions. As has recently become clear, TPPs across the nation were the primary financial victims of Defendants' unlawful schemes, having been duped by each Defendant into paying billions of dollars for off-label, ineffective, and unsafe TRT drug prescriptions.

II. PARTIES

30. Plaintiff MMO, on behalf of itself and its subsidiaries, is a not-for-profit mutual insurance company organized under Ohio law with its principal place of business in Cleveland, Ohio, and is a proposed class representative. The oldest health care insurer in Ohio, MMO provides individual and group health benefits, Medicare supplemental insurance, and other ancillary products, such as vision, dental, and prescription drug coverage. Through its wholly-owned subsidiary Medical Mutual Services, LLC, MMO also offers administrative services contracts to self-insured groups. MMO contractually outsources aspects of the management of the pharmacy benefits it provides to its members to a Pharmacy Benefit Manager ("PBM"). At all times material hereto, MMO reimbursed for one or more of Defendants' drug products. During the Class Period MMO has paid for thousands of TRT drug prescriptions.

31. Defendant Solvay S.A. is a corporation incorporated in Belgium. Its principal place of business is Rue du Prince Albert 33, B-1050 Brussels—Belgium. At all times material hereto, Solvay S.A. has conducted extensive business throughout the United States.

32. Defendant Solvay America, Inc. is a corporation incorporated in the state of Delaware. Its principal place of business is 3333 Richmond Avenue, Houston Texas 77098. Defendant Solvay America, Inc. conducts extensive business throughout the United States, including in the State of Illinois. Solvay America, Inc. may be served through its registered agent, Corporation Service Company d/b/a CSC-Lawyers Inco., 211 E. 7th Street, Suite 620, Austin, Texas 78701. At all times relevant to this Complaint, Solvay America, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription testosterone replacement therapy drugs sold under the name AndroGel throughout the United States, including in the State of Illinois.

33. Defendant Solvay North America, LLC is a limited liability corporation incorporated in the State of Delaware. Its principal place of business is 3333 Richmond Avenue, Houston, Texas 77098. Defendant Solvay North America, LLC conducts extensive business throughout the United States, including in the State of Illinois. Solvay North America, LLC may be served through its registered agent, Corporation Service Company d/b/a CSC-Lawyers Inco, 211 E. 7th Street, Suite 620, Austin, Texas 78701. At all times relevant to this Complaint, Solvay North America, LLC was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription testosterone replacement

therapy drugs sold under the name AndroGel throughout the United States, including in the State of Illinois.

34. Defendant Solvay Pharmaceuticals Sarl is a corporation incorporated in Luxembourg. Solvay Pharmaceuticals Sarl conducts extensive business throughout the United States, including in the State of Illinois.

35. Defendant Solvay Pharmaceuticals, Inc. is a corporation incorporated in the State of Delaware with its principal place of business in Marietta, Georgia. Defendant Solvay Pharmaceuticals, Inc. conducts extensive business throughout the United States, including in the State of Illinois. Solvay Pharmaceuticals, Inc. may be served through its registered agent, CT Corporations Systems, 1201 Peachtree Street, NE, Atlanta, Georgia, 30361. At all times relevant to this Complaint, Solvay Pharmaceuticals Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription testosterone replacement therapy drugs sold under the name AndroGel throughout the United States, including in the State of Illinois.

36. Defendant Abbott Products, Inc. is a Georgia corporation whose principal business is the development, manufacture, and sale of health care products and services, including pharmaceuticals. Abbott Products, Inc. conducts extensive business throughout the United States, including in the State of Illinois. On February 16, 2010, Abbott Laboratories acquired Solvay Pharmaceuticals for EUR 4.5 billion ($6.2 billion). Abbott Laboratories' purchase of Solvay Pharmaceuticals has resulted in the substantial continuity of Solvay Pharmaceuticals' business practices. After the acquisition, Abbott Laboratories renamed Solvay Pharmaceuticals "Abbott Products, Inc." Abbott Products, Inc. has continued to produce and

market Solvay Pharmaceuticals' products, such as AndroGel. Abbott Products, Inc. has retained some of Solvay Pharmaceuticals' employees in doing so. Abbott Products, Inc. may be served through its registered agent, CT Corporations Systems, 350 N. St. Paul St., Suite 2900, Dallas, Texas 75201. At all times relevant to this Complaint, Abbott Products, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription testosterone replacement therapy drugs sold under the name AndroGel throughout the United States, including in the State of Illinois.

37. Defendant AbbVie Inc. ("AbbVie") was incorporated in Delaware on April 10, 2012. AbbVie's principal place of business is Chicago, Illinois. AbbVie became an independent entity on January 1, 2013. AndroGel, while initially developed, marketed, and sold by Solvay and later Abbott Products, is now marketed and sold by AbbVie. Defendant AbbVie conducts extensive business in the United States, including in the State of Illinois. At all times relevant to this Complaint, AbbVie was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription testosterone replacement therapy drugs sold under the name AndroGel throughout the United States, including in the State of Illinois.

38. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Prior to 2013, Abbott engaged in the global business of development, manufacturing, marketing and sale of prescription drugs and related products. At the end of 2012, Abbott separated into two companies, one focused on the development and sale of medical products (Abbott), and the other focused on the development

and sale of research-based pharmaceuticals (AbbVie). Defendant Abbott conducts extensive business in the United States, including in the State of Illinois. At all times relevant to this Complaint, Abbott was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription testosterone replacement therapy drugs sold under the name AndroGel throughout the United States, including in the State of Illinois.

39. Collectively, Solvay S.A., Solvay America, Inc., Solvay North America, LLC, Solvay Pharmaceuticals Sarl, Solvay Pharmaceuticals, Inc., Abbott Products, Inc., AbbVie Inc. and Abbott shall be referred to herein as "the AbbVie Defendants."

40. Defendant Auxilium Pharmaceuticals, Inc., is a Delaware corporation which has its principal place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087. Auxilium has conducted business and derived substantial revenue from sales of Testim and Testopel throughout the United States, including in the State of Illinois. At all times relevant to this Complaint, Auxilium was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription testosterone replacement therapy drugs sold under the names Testim and Testopel throughout the United States, including the State of Illinois.

41. Defendant Eli Lilly and Company is a corporation organized and existing under the laws of Indiana with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Defendant Lilly USA, Inc. is a limited liability company operating as a wholly owned subsidiary of Defendant Eli Lilly and Company (hereinafter collectively referred to as

"Lilly"), with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. At all times material hereto, Defendant Lilly conducted business and derived substantial revenue from sales of Axiron throughout the United States, including within the State of Illinois. At all times material hereto, Lilly was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription testosterone replacement therapy drug sold under the name Axiron throughout the United States, including the State of Illinois.

42. Defendant Acrux Limited ("Acrux") is a foreign corporation organized and existing under the laws of Australia, with its principal place of business at 103-113 Stanley Street, West Melbourne VIC 3003, Australia. Acrux originally developed Axiron and owns the intellectual property rights to Axiron. In March of 2010, Acrux and Eli Lilly and Company entered into an exclusive worldwide license agreement for the commercialization of Axiron. Defendant Lilly has agreed to pay Acrux royalties for Axiron sales based on milestones agreed to in the license agreement. On November 23, 2010, Axiron received FDA approval. At all times relevant herein, Acrux was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Axiron in the State of Illinois and is therefore subject to the jurisdiction and venue of the State of Illinois. Acrux has conducted business in and derived substantial revenue from within the State of Illinois.

43. Hereinafter, Defendants Eli Lilly and Company, Lilly USA, Inc., and Acrux will be referred to as "Defendant Lilly" or "Eli Lilly."

44. Defendant Actavis plc is a foreign corporation organized and existing under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin

2, Ireland and administrative headquarters located at Morris Corporate Center III, 400 Interpace Parkway Parsippany, New Jersey 07054. At all times relevant herein, Actavis plc was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Androderm, in the State of Illinois and is therefore subject to the jurisdiction and venue of the State of Illinois. Actavis plc has conducted business and derived substantial revenue from within the State of Illinois.

45. Defendant Actavis Pharma, Inc., formerly known as Watson Pharmaceuticals, Inc., is a domestic corporation organized and existing under the laws of the state of Nevada and maintains its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. By way of background, Watson Pharmaceuticals acquired Actavis Group in 2012 and announced shortly thereafter that, as of January 2013, it would change its name to Actavis, Inc. Watson Pharmaceuticals, Inc. had acquired the original manufacturer of Androderm, TheraTech, in 1999. At all times material hereto, Actavis Pharma, f/k/a Watson Pharmaceuticals, Inc., was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Androderm in the State of Illinois and is therefore subject to the jurisdiction and venue of the State of Illinois. Actavis Pharma, Inc., f/k/a Watson Pharmaceuticals, Inc., has conducted business and derived substantial revenue from within the State of Illinois.

46. Defendant Watson Laboratories, Inc. is a domestic corporation organized and existing under the laws of the state of Delaware and previously operated at 577 Chipeta Way, Salt Lake City, Utah 84108, and with its current principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. At all relevant times herein, Defendant Watson Laboratories, Inc, a subsidiary of Actavis, Inc., was engaged in the research,

development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Androderm, in the State of Illinois and is therefore subject to the jurisdiction and venue of the State of Illinois. Watson Laboratories, Inc. has conducted business and derived substantial revenue from within the State of Illinois.

47. Defendant Anda, Inc. is a domestic corporation organized and existing under the laws of the state of Florida and maintains its principal place of business at 2915 Weston Road Weston, Florida 33331. At all relevant times herein, Defendant Anda, Inc, a subsidiary of Actavis, plc, was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Androderm, in the State of Illinois and is therefore subject to the jurisdiction and venue of the State of Illinois. Anda, Inc. has conducted business and derived substantial revenue from within the State of Illinois.

48. Throughout the Complaint, "Defendant Actavis" or "Actavis" collectively refers to Actavis, Inc., Actavis plc, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Anda, Inc.

49. Defendant Endo Pharmaceuticals, Inc. (hereinafter "Endo"), formerly Endo Laboratories, LLC, and a subsidiary of Endo Pharmaceuticals Holdings, Inc., is a corporation organized and existing under the laws of Delaware with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. By way of background, Cellegy Pharmaceuticals, Inc. originally developed Fortesta and sought FDA approval in 2002. In November 2006, the NDA for Fortesta was transferred to ProStraken Pharmaceuticals, Inc. Before the drug was approved by the FDA in December 2010, Endo acquired the U.S. rights for Fortesta from ProStraken Pharmaceuticals and subsequently brought Fortesta to market. At all times material hereto, Endo was engaged in the research, development, manufacture, sales,

marketing, and/or distribution of pharmaceutical products, including Fortesta in the State of Illinois and is therefore subject to the jurisdiction and venue of the State of Illinois. Endo has conducted business and derived substantial revenue from Fortesta within the State of Illinois.

III. JURISDICTION AND VENUE

50. This Court has subject matter jurisdiction over all of the claims of Plaintiff and the Class Members pursuant to 28 U.S.C. § 1331, because the claims in this action arise under the laws of the United States; pursuant to 18 U.S.C. § 1964, because this Court has jurisdiction to prevent, remedy, and restrain violations of 18 U.S.C. § 1962 (RICO); pursuant to 28 U.S.C. § 1332(d) (CAFA) because there is minimal diversity of citizenship among the parties and the amount in controversy exceeds $5 million, exclusive of interest and costs; and pursuant to 28 U.S.C. § 1367(a), because this Court has supplemental jurisdiction over all non-federal claims in this action that form part of the same case or controversy as those within the Court's original jurisdiction.

51. Venue is proper in this District under 28 U.S.C. § 1391 because all Defendants engaged in substantial conduct relevant to Plaintiff and the Class Members' claims within this District, and all Defendants have caused harm to Plaintiff and the Class Members residing within this District. Venue is also proper in this District under 18 U.S.C. § 1965(a), which provides that "[a]ny civil action or proceeding under this chapter against any person may be instituted in the district court of the United States for any district in which such person resides, is found, has an agent, or transacts his affairs." All Defendants received substantial compensation from the sales of their respective TRT drug(s) in this District, all Defendants made misrepresentations and material omissions about their respective TRT drug(s) in this District, and all Defendants can be found, have an agent, and/or transact their affairs in this District.

IV. FACTUAL ALLEGATIONS: TRT DRUGS' BACKGROUND

52. New pharmaceutical drugs may not be marketed in the United States until the sponsor of the pharmaceutical has proven to the FDA that the drug is safe and effective for specific indications at specified doses. 21 U.S.C. § 355(b); 21 C.F.R. § 310.3(h)(f). The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also approved by the FDA. Importantly, no law or regulation prevents a pharmaceutical manufacturer from unilaterally adding or strengthening a warning in the pharmaceutical's label. In addition, although it is not unlawful for physicians to prescribe approved drugs for indications or at dosages different than those set forth in a drug's labeling (referred to as "off-label" use), the Food, Drug, and Cosmetic Act ("FDCA") generally prohibits drug companies from marketing or promoting approved drugs for uses other than those set forth in the drug's approved labeling. 21 U.S.C. § 355(b).

53. The AbbVie Defendants' AndroGel is a gel containing synthetic testosterone developed originally by Unimed Pharmaceuticals, Inc., and currently marketed by the AbbVie Defendants. AndroGel was first marketed in the United States by Solvay S.A., a Belgian pharmaceutical manufacturer, through its U.S.-based subsidiaries. Solvay was later acquired by Abbott on February 16, 2010 for 4.5 billion Euros ($6.2 billion). AndroGel was by far Solvay's largest asset at the time of Abbott's acquisition. The gel is applied to the shoulder, upper arms, and/or the abdomen once daily so that the testosterone can be absorbed through the skin, or transdermally. AndroGel 1% was approved by the US FDA on February 28, 2000 for the treatment of primary and hypogonadotrophic hypogonadism. AndroGel 1.62% was approved on April 29, 2011 for the treatment of primary and hypogonadotrophic hypogonadism. The

AndroGel product originally came in individual packets. Defendant Solvay launched new packaging for AndroGel on September 8, 2004 in the form of a metered pump.

54. Defendant Auxilium's Testim is a gel containing synthetic testosterone developed by Defendant Auxilium. Testim is available in a 1% concentration and in a single, premeasured tube packaging only. The gel is applied to the shoulder, upper arms, and/or the abdomen once daily so that the testosterone can be absorbed through the skin, or transdermally. Testim was approved by the US FDA on October 31, 2002 for the treatment of primary and hypogonadotrophic hypogonadism. Testim is manufactured and marketed by Defendant Auxilium Pharmaceuticals, Inc. On May 21, 2012, Auxilium and GlaxoSmithKline LLC ("GSK") announced a Testim co-promotion agreement to last through September 30, 2015, the stated goal of which was "to expand our reach to U.S. physicians who treat men with low testosterone and its resulting symptoms, known as hypogonadism, which we believe is a prevalent, but poorly recognized condition." GSK's press release stated that GSK's sales force would focus primarily on primary care physicians, and that Testim would "complement GSK's existing portfolio of products[,]" including a "range of cardiovascular, metabolic and urology" products. After the GSK co-promotion agreement was terminated, Defendant Auxilium promoted Testim through the Primera sales force, which "consists of 150 representatives currently devoted to strategic targeting of urologists, endocrinologists, and certain high prescribing primary care physicians."

55. Defendant Auxilium's Testopel pellets are cylindrically shaped pellets 3.2mm (or 1/8 in.) in diameter and approximately 9mm in length, consisting of seventy-five (75) mg of crystalline testosterone. When implanted subcutaneously, the pellets slowly release the hormone for a long acting androgenic effect. The dosage guideline for Testopel testosterone pellets for

replacement therapy in androgen-deficient males is 150mg to 450mg subcutaneously every 3 to 6 months. Testopel is a generic product that was approved by the FDA on July 13, 1972, and is approved to treat men with primary and hypogonadotrophic hypogonadism. The ANDA holder is Actient Pharmaceutical Holdings, LLC, which was acquired by Defendant Auxilium on April 29, 2013. Defendant Auxilium promotes Testopel through its Innovia sales force, which Defendant Auxilium recently "increased by 50% … to increase depth of TESTOPEL utilization and provide greater penetration into remaining untapped urologist audience."

56. Defendant Lilly's Axiron is a testosterone gel topical solution (2%) available as a metered-dose pump. One pump actuation delivers 30mg of testosterone to be applied to the axilla (under the arms) with the provided applicator. Axiron was developed by Defendant Acrux, Ltd, which entered into an exclusive commercialization license agreement with Defendant Lilly. Defendant Lilly submitted Axiron for approval in the United States, which the FDA granted on November 23, 2010, for the treatment of primary and hypogonadotrophic hypogonadism.

57. Defendant Actavis's Androderm (testosterone transdermal system) is a prescription TRT medication in the form of a transdermal patch, manufactured by TheraTech Inc. and Actavis Inc. (formerly Watson Pharmaceuticals), and was approved for use (2.5 mg and 5.0 mg) by the FDA on September 29, 1995 for the treatment of primary and hypogonadotrophic hypogonadism. On October 11, 2011, the FDA approved 2 mg and 4 mg formulations of Androderm. From 1995 through 1999, Androderm was marketed by SmithKline Beecham under an agreement with TheraTech. In 1999, when Watson purchased TheraTech, it began marketing Androderm through its own sales force and a contracted sales force through InVentiv Health.

58. Defendant Endo's Fortesta is a patented two percent (2%) testosterone transdermal gel approved by the FDA on December 29, 2010 for treatment of primary and

hypogonadotrophic hypogonadism. Fortesta is delivered transdermally and is applied to the skin in the form of a gel. In August 2009, Endo entered into a License and Supply Agreement (the ProStrakan Agreement) with Strakan International Limited, a subsidiary of ProStrakan Group plc (ProStrakan), for the exclusive right to commercialize Fortesta® Gel in the United States. Endo launched Fortesta® Gel in the first quarter of 2011. In a March 3, 2011 press release announcing the launch, Endo stated that the "introduction of FORTESTA Gel in the U.S. comes at a time when only about 1.3 million (9 percent) of the estimated 14 million men with Low T are actually receiving treatment." On December 27, 2011, Endo entered into a Sales and Promotional Services Agreement with Ventiv Commercial Services, LLC (Ventiv), effective as of December 30, 2011. Under the terms of the Ventiv Agreement, the Ventiv Field Force promoted Fortesta® Gel, and its sales representatives were required to perform face-to-face, one-on-one discussions with physicians and other health care practitioners to promote these products.

59. None of the aforementioned TRT drugs was exempt from the prohibition against commercializing off-label uses, pursuant to 21 U.S.C. § 355(i).

60. This regulatory scheme is designed to protect physicians, patients and consumers by insuring that pharmaceutical companies do not promote drugs for uses other than those proven to be safe and effective before an independent, scientific governmental body.

61. The FDA has approved all TRT drugs solely for treatment of male patients with particular types of hypogonadism. For example, the AndroGel label reads:

> AndroGel is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:
>
> Primary hypogonadism (congenital or acquired) – testicular failure due to cryptorchism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.

> Hypogonadotrophic hypogonadism (congenital or acquired) – idiopathic gonadotropin or … LHRH … deficiency or pituitary-hypothalamic injury from tumor, trauma, or radiation.

62. In June 2007, Solvay announced that it had submitted a new drug application ("NDA") for AndroGel for treatment of Constitutional Delay in Growth and Puberty in male adolescents ages 13 to 17 years old. The FDA still has not approved this use.

63. In May 2009, after receiving reports of adverse effects in children who were inadvertently exposed to testosterone through secondary contact with a person being treated with gel-based TRT drugs, the FDA required that Defendants with testosterone gel products include black box warnings on their products, namely AndroGel, Testim, Fortesta, and Axiron. Although the labels for these products warned users to wash hands after application of the product and to cover the treated area with clothing and warned of the potential risk of transfer to female partners, neither label mentioned any risk of transfer to children.

64. Signs and symptoms in the exposed children included inappropriate enlargement of the genitalia, premature development of pubic hair, advanced bone age, increased libido, and aggressive behavior. In addition, some of the children had to undergo invasive diagnostic procedures. In most cases, these adverse events regressed once the child was no longer exposed to testosterone products. In a few cases, the adverse effects experienced by the children did not regress; for example, some children's enlarged genitalia failed to return to age-appropriate size and/or their bone age remained higher than the children's chronological age.

V. FORMATION OF THE UNLAWFUL TRT DRUGS MARKETING ENTERPRISES

65. Beginning approximately in 2000 and continuing to the present, each Defendant implemented a marketing, advertising and promotion campaign by combining its own respective

significant personnel and financial resources with a discreet and identifiable number of medical marketing firms and peer-influencing physicians through which Defendants (i) falsely and deceptively oversold the efficacy of the TRT drugs, (ii) failed to adequately warn of, and affirmatively misled the medical community regarding the severe side effects of the TRT drugs, and (iii) unlawfully promoted the TRT drugs for usage in populations for which it had not received FDA approval and for which the efficacy and side effects had not been established through adequate clinical evidence. These associations-in-fact created by each Defendant are denominated in this Complaint as the AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta Peer Selling Enterprises, the AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta Publication Enterprises, and the AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta Direct-to-Consumer Enterprises (collectively "the Enterprises"). Each Defendant and its associated participants established the respective Enterprises to accomplish the common goal of causing increased prescribing activity of the Defendant's TRT drug(s) for off-label uses for which the TRT drug(s) were not proven to be safe, effective, or useful. The schemes were accomplished through fraudulent, or false and deceptive, claims of efficacy and safety, medical usefulness, and for unlawful, off-label purposes.

66. First, to execute their Peer Selling Enterprises successfully, each Defendant had to create parallel marketing structures that appeared independent from the ordinary promotion forces – they each did so both to avoid federal regulations concerning off-label promotion and to create the façade of independence behind the misleading messages of safety, efficacy and non-indicated usage they each wished to promote. Each Defendant targeted primarily speaking events, seminars, continuing medical education ("CME") events, or other physician gatherings. Defendants each worked with and paid vendor participants to create content for such speaking

events that mirepresented the safety, efficacy, and usefulness of Defendants' TRT drug(s) for off-label uses, and then paid physician participants to serve as faculty or lecturers at such events to deliver the disguised promotional messages to unsuspecting physician attendees.

67. Second, to execute their Publication Enterprises successfully, each Defendant had to generate and publish favorable study results (negative study results were sequestered) and articles that appeared to emanate from independent physicians. Defendants proceeded by designing studies with predetermined results that consistently focused almost exclusively on off-label uses of TRT drugs. Adequately powered safety studies for such off-label uses were deliberately avoided. Each Defendant maintained exclusive control over the study protocols, the selection of investigators and/or external authors, and the study results. Investigators were required to sign non-disclosure agreements, such that Defendants maintained exclusive control over which study results were made public. Assuming a particular study yielded positive results, each Defendant then retained one or more medical communications vendors to ghostwrite a publication with the assistance of Defendant's employees. Undue importance was given to injecting promotional messagaging into such articles. Finally, the articles were published as unbiased scientific literature under the names of the external authors/investigators; such authors were paid to lend their names and reputations for a fee. Finally, each Defendant ordered reprints of such studies by the thousands, and each Defendant's sales force was instructed to deliver reprints to physicians on sales calls, while not disclosing the process by which these publications were generated. These studies were designed to give the appearance of independent peer-to-peer credibility for study results that were cherry-picked and for articles that were designed much the same as a sales aid.

68. Third, to execute their Direct-to-Consumer Enterprises (hereinafter "DTC Enterprises") successfully, each Defendant had to disseminate marketing materials or advertisements that discussed or suggested to patients that the TRT drug(s) being promoted were safe and effective for off-label uses, and that discussed medical conditions or disease states, generally known as "unbranded promotions", to redefine and expand the definition of hypogonadism beyond the FDA-approved indications.

69. All of the goals of the Enterprises were intentionally complementary and mutually reinforcing. The Defendants' respective Enterprises, individually and collectively, succeeded in distorting and polluting the medical discourse and medical literature surrounding the TRT drugs to such a degree that physicians and patients were rendered incapable of making objective and informed decisions concerning the appropriateness of prescribing TRT drugs for off-label and label-expanding usage.

A. Formation of the Illegal Peer Selling Enterprises

70. Defendants' respective Peer Selling Enterprises centered on each hosting numerous events where doctors trained and/or approved by Defendants would falsely oversell the efficacy and safety of TRT drugs, and the sponsoring Defendant's TRT drug(s) in particular, and would provide favorable information on the off-label use of such TRT drug(s), often under conditions where physicians would be compensated for attending the presentation. Defendants each have funded and continue to fund scores of such events between approximately 2000 to present.

71. Because Defendants were prohibited from directly producing such events, they each created and controlled a Peer Selling Enterprise composed of medical marketing firms (the "vendor participants") and several dozen physicians (the "physician participants") who routinely

promoted one or more of the TRT drugs to other physicians in venues all across the country. Defendants each maintained sufficient control over their respective Peer Selling Enterprises to select and approve the content of the programs and the physician participants that would deliver the off-label message. Physicians who were not receptive to promoting the TRT drug(s) for the off-label uses were not considered for inclusion in the respective Peer Selling Enterprises. The physicians (mostly primary care physicians) who attended these events were deceived into thinking that the events were educational in nature and independent from the control of the sponsoring Defendant(s).

72. The Peer Selling Enterprises employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy of the TRT drug(s) for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of the TRT drug(s) for both approved indications and for a variety of off-label uses; (c) deliberately concealing negative findings or the absence of positive findings relating to the off-label uses of the TRT drug(s); (d) wrongfully and illegally compensating physicians for causing the prescribing of the TRT drug(s); (e) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of the TRT drug(s) for both on-label and off-label uses, and then disseminating copies of such studies by the thousands; (f) intentionally misrepresenting and concealing Defendants' role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell the TRT drug(s) to off-label markets; and (g) intentionally misrepresenting and concealing the financial ties between Defendants and other participants in the Enterprises.

73. Each Defendant's scheme reaped significant financial gain. From 2000 to present, each Defendant's revenues from the sale of their TRT drug(s) soared into the millions and billions of dollars. Eventually, as a result of each Defendant's Peer Selling Enterprise efforts and unbeknownst to Plaintiff and Class Member TPPs, the vast majority of all TRT drug prescriptions were for off-label uses. Sales of each drug have grown at a significant rate each year.

74. All of the participants in the Defendants' Peer Selling Enterprises associated with the respective Defendants with the common purpose of aiding them in marketing that Defendant's TRT drug(s) for off-label uses and to achieve "market expansion" of these uses. Each of the participants received substantial revenue or other consideration from each Defendant for their efforts in the scheme to promote the TRT drug(s) off-label. The more successful these marketing events were, the more events there would be in the future and the more fees each of the participants would receive for participating in the events. For these reasons, all of the participants knowingly and willingly agreed to assist each of the Defendants in their off-label promotion of the TRT drug(s), notwithstanding the fact that such a promotional campaign required the systematic repetition of false and misleading statements to, and the commercial bribery (through kickbacks) of, a score or more physicians throughout the United States, and that the promotion of any of the TRT drugs for off-label indications by Defendants was illegal.

75. Each Defendant exercised control over and participated in its respective Peer Selling Enterprise. Each Defendant compensated the other participants for their efforts, and controlled the money flow to the participating vendors and physicians. Defendants each closely monitored all events to insure the expected representations and marketing messages related to the off-label uses of their respective TRT drug(s) were made to physicians attending the events.

Following such events, each Defendant tracked attending physicians' prescribing habits to ensure that the messaging was successful in causing prescribing activity for their respective TRT drug(s).

a. ***Role of Medical Marketing Firms in Peer Selling Enterprises***

76. Third party medical marketing firms were critical to each Defendant's scheme to promote its TRT drug(s) off-label from the scheme's inception. Each Defendant's marketing plans called for off-label information concerning its TRT drug(s) to be widely disclosed in continuing medical education programs, "consultants' meetings" (also called "advisory boards"), and other programs where physicians could instruct other doctors how to use each Defendant's TRT drug(s) for unapproved indications. Bona fide continuing medical education programs and similar educational events are exempt from FDA rules prohibiting off-label promotion because the sponsoring organization (which was often a nonprofit, like a medical school) was independent and was supposed to control the content of such programs. In practice, however, these programs were produced with the assistance of third party medical marketing firms, some of whom are listed below, and these firms, acting at the direction of the sponsoring Defendant(s), supplied content and controlled the selection of presenting physicians.

77. Each Defendant's respective and collective marketing strategies turned the proper practices for presenting continuing medical education programs on their head. Instead of accredited institutions planning independent programs and then approaching third party vendors and financial sponsors, each Defendant intended to create turnkey medical programs, with financing already included, and then find "independent" institutions that would present the package in the format each Defendant and its Enterprise created.

78. Among the information each Defendant, the participating vendors, and the participating physicians deliberately omitted from the events they sponsored was the following: (a) the complete lack of adequate clinical trial evidence to support the off-label uses of TRT drugs; (b) negative clinical trial results that demonstrated TRT drugs were no more effective than other, less costly, medications; (c) suppression negative evidence that TRT drugs did not work for off-label conditions; (d) information that virtually all publications and studies that allegedly supported the off-label use of TRT drugs had been funded by one or more Defendant(s); (e) information that virtually all publications and studies that allegedly supported the off-label use of TRT drugs had been initiated by one or more Defendant(s) pursuant to a corporate marketing plan designed to increase off-label sales; (f) information that the participating doctors who were conducting the peer selling had been paid substantial subsidies to use Defendants' TRT drugs on their patients for off-label purposes; (g) that the events the physicians were attending were neither fair nor balanced and were created to insure the physicians would not hear a fair and balanced examination of TRT drugs for off-label uses; (h) information that the events were not funded, as advertised, by an "unrestricted" grant from each Defendant, but that the grants were conditioned upon the participating vendors and sponsoring institutions putting on presentations that painted the off-label use of TRT drugs in the most favorable light; and (i) information with respect to dangerous side effects revealed through each Defendant's internal research, adverse event reports, and independent research.

79. Each of the participating vendors was in regular communication with the respective Defendant(s). In connection with major medical congresses or conventions of the specialists that were the target of the off-label promotion campaign, the participating vendors coordinated their events to ensure their off-label message reached the most physicians in the

most effective manner. The participating vendors were also in regular communication with many of the participating physicians, and individual participating physicians gave the same presentation (or a substantially equivalent presentation) at different participating vendors' events, per each sponsoring Defendant's directions.

80. The planning and coordination of all of these events by the third party medical marketing firms required extensive use of the wires and mails, including the mailing of invitations to physicians, the mailing of proposals to the accrediting institutions, booking of hotels and airplane tickets, the arrangement of meals, the scheduling of teleconference calls, the development and modification of the tactical plans, and the coordination of the content of the presentations on TRT drugs to be presented at the event.

81. Firms that participated in the AndroGel Peer Selling Enterprise include co-promoters, third party advertisers, proliferation firms and outside consultants such as: Dowden Health Media (110 Summit Ave., Montvale, NJ 07645); Edelman Worldwide (250 Hudson Street, 16th Floor, New York, NY 10013); EDU-Medical Management, Inc. (1621 18th St, Denver, CO 80202); Excerpta Medica (Apollo Building, Herikerbergweg 17, 1101 CN Amsterdam, Netherlands); Paddock Laboratories, Inc. (3940 Quebec Ave. N., Minneapolis, MN 55427); Par Pharmaceutical Companies (300 Tice Boulevard, Woodcliff Lake, NJ 07677); TAP Pharmaceutical Products, Inc. (675 North Field Drive, Lake Forest, IL 60045); Watson Pharmaceuticals, Inc. (Euro House, Euro Business Park, Little Island Business Park, Cork, Ireland); Digitas Health (100 E. Penn Square, Philadelphia, PA 19107); Abelson Taylor (33 W. Monroe St., Chicago, IL 60603); CogniMed, Inc. (70 S. Orange Ave., Livingston, NJ 07039); Dannemiller (5711 Northwest Parkway, San Antonio, TX 78249); Curatio CME Institute (100 Campbell Boulevard, Suite 103 Exton, PA 19141); Applied Clinical Education (545 West 45th

St, Floor 8, New York, NY 10036); PeerView Press (174 W. 4th Street, Suite 182, New York, NY 10014); Education Awareness Solutions (One Selleck Street, Norwalk, CT, 06855); Practicing Clinicians Exchange (One Dock Street, Suite 510, Stamford, CT 06902); Curry Rockefeller Group (660 White Plains Road, Tarrytown, NY 10591); and Covance Periapproval Services (555 E. North Lane # 6000, Conshohocken, PA 19428).

82. Firms that participated in the Testim and Testopel Peer Selling Enterprise include co-promoters, third party advertisers, proliferation firms and outside consultants such as: e-tractions (Watermanstraat 40, Apeldoorn, Netherlands); GlaxoSmithKline, LLC (GSK House, 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom); Heartbeat Ideas (200 Hudson St., 9th Floor, New York, NY 10013); Lathian Health (246 Industrial Way West, Avenue at the Common, Eatontown, NJ 07724); Transit Creative Brand Design Group (45 Wilder Street, #4, San Francisco, CA 94131); MedVal Scientific Information Services, LLC (30 Vreeland Drive, Building 30 Suite 2, Skillman, NJ 08558); MedReviews, LLC (1333 Broadway, New York, NY 10018); CogniMed, Inc. (70 S. Orange Ave., Livingston, NJ 07039); Dannemiller (5711 Northwest Parkway, San Antonio, TX 78249); Area 23 A DraftFCB Company (622 Third Avenue, 3rd Floor, New York, NY 10017); TRG Communications, LLC (www.trgcommunications.us); and MCS Healthcare Public Relations (1420 U.S. Highway 206 North Suite 100 Bedminster, New Jersey 07921).

83. Firms that participated in the Axiron Peer Selling Enterprise include co-promoters, third party advertisers, proliferation firms and outside consultants such as: Gargano Creative Group (New York, NY); Grey Group (200 Fifth Avenue, New York, NY 10010); Acrux, Ltd. (103-113 Stanley Street, West Melbourne VIC 3003, Australia); Abelson Taylor (33 W. Monroe St., Chicago, IL 60603); The Hobart Group (240 Main Street, Suite 400 Gladstone,

NJ 07934); McCann Torre Lazur Group (20 Waterview Blvd., Parsippany, NJ 07054); GSW Advertising, LLC (1180 Avenue of the Americas, 10th Floor, New York, NY 10036); FCB Health (100 W. 33rd Street, New York, NY 10001); The Agency Inside, A Harte Hanks Company (777 Township Loop, Suite 300, Yardley, PA 19067); AccelMed, LLC (900 E. 96th Street, Suite 125, Indianapolis, Indiana 46240); CME Outfitters, LLC (10319 Westlake Dr. # 106, Bethesda, MD 20817); CogniMed, Inc. (70 S. Orange Ave., Livingston, NJ 07039); Continuing Education Alliance, LLC (One Dock Street, Suite 510, Stamford, CT 06902); Educational Review Systems, Inc. (3015 Shannon Lakes Drive, Suite 303, Tallahassee, Florida 32309); Elsevier, Inc. – Elsevier Office of Continuing Medical Education (65 East Butler Avenue, Suite 102, New Britain, PA 18901); Paradigm Medical Communications, LLC (523 Route 303, Orangeburg, NY 10962); Foundation for Men's Health, Inc. (www.foundationformenshealth.org); Japri Planners Corporation (P.O. Box 1600 Suite 272 Cidra, Puerto Rico 00739); Med-IQ, LLC (5523 Research Park Drive, Suite 210, Baltimore, MD 21228); Miller Medical Communications, LLC (501 5th Ave., New York, NY 10017); North American Center for Continuing Medical Education, LLC (104 Windsor Center Drive, Suite 200, East Windsor, NJ 08520); Postgraduate Healthcare Education, LLC 777 Passaic Ave., Suite 380, Clifton, NJ 07012); Prova Education, Inc. (500 Office Center Drive, Suite 300, Fort Washington, PA 19034); PVI PeerView Institute for Medical Education, Inc. (174 W. 4th Street, Suite 182, New York, NY 10014); Suasion Group, LLC – Educational Awareness Solutions (One Selleck Street, Norwalk, CT 06855); Ultimate Medical Academy LLC – dba Global Education Group (2 East Congress Street, Suite 900 Tucson, AZ 85701); Ultimate Medical Academy LLC – Med Learning Group (26 W. 17th Street, New York, NY 10011); WebMD Health Corp. – Medscape LLC (825 Eighth Avenue, 11th Floor, New York, NY 10019);

American Health Resources, Inc. (130 Liberty Street, Suite 13A, Brockton, MA 02301); Asante Communications, LLC (800 Third Avenue, 23rd Floor, New York, NY 10022); Integritas Communications (95 River Street, Suite 5C, Hoboken, NJ 07030); i3 Statprobe dba inventive Health clinical (504 Carnegie Center, Princeton, NJ 08540).

84. Firms that participated in the Androderm Peer Selling Enterprise include: Grant Downing Education (600 Grant Street, Suite 510, Denver, CO 80203).

85. Firms that participated in the Fortesta Peer Selling Enterprise include Dannemiller (5711 Northwest Parkway, San Antonio, TX 78249); CogniMed (70 S. Orange Ave., Livingston, NJ 07039); Postgraduate Institute for Medicine (367 Inverness Pkwy, Englewood, CO 80112); Miller Medical Communications, LLC (501 5th Ave., New York, NY 10017); and Watermeadow Medical (Range Rd, Witney, Oxfordshire OX29, United Kingdom).

86. Plaintiff at this time does not know the identities of all the vendor participants involved in respective Peer Selling Enterprises.

b. ***Role of Physicians in the Peer Selling Enterprises***

87. One of the principal strategies pursued by all Defendants in their respective Peer Selling Enterprises was to target key physicians to serve as "thought leaders." These doctors promoted the assigned TRT drug(s) to their peers through peer selling programs by (i) touting that TRT drug's supposed off-label uses; (ii) claiming that TRT drugs were being widely used by other physicians for off-label uses; and (iii) claiming that they were privy to the latest clinical data that had not been released yet, but which would support off-label use.

88. To lure physicians to participate in the Peer Selling Enterprises, each Defendant approached target doctors and informed them of an interest in funding research opportunities and clinical trials at their institutions. Doctors who were willing to speak favorably about one or

more TRT drugs could receive substantial funds in the form of research grants or other monies. In addition, these doctors were frequently remunerated for other less-defined services, including "consulting" and "advisory board" services. Each Defendant instructed its sales departments to select doctors at the major teaching hospitals to become TRT drug "experts" or opinion and thought leaders ("OTLs") who would in turn deliver the TRT message to other physicians to grow sales. This was done formally to other physicians at marketing events or informally to colleagues within a hospital or medical practice, or at a dinner or lunch roundtable.

89. Having recruited these physicians, each Defendant's Peer Selling Enterprise created an explosion in the off-label use of TRT drugs by artificially creating the perception that physician specialists were clinically using TRT drugs and investigating with positive results their efficacy in off-label uses on their own initiative, and not as a result of the illegal marketing activities and inducements. Each Defendant developed a stable of physicians to create this perception. Each Defendant, principally through the vendor participants to minimize reportable conflicts of interest, paid these physicians to induce them to write journal articles and letters to the editor that favorably discussed the off-label use of TRT drugs. Each Defendant also paid these physicians (in addition to providing free travel to resorts, free lodging and free meals) to induce them to give talks at medical education seminars, advisory boards, consultants' meetings, speakers bureaus and similar events where the primary focus of the discussion was the off-label use of TRT drugs. The physicians who accepted these benefits and agreed to promote one or more TRT drugs off-label to other doctors were physician participants in the respective Defendant's Peer Selling Enterprise(s). The individual physician participants received tens of thousands of dollars, and in some cases hundreds of thousands, to promote the off-label uses of TRT drug(s). Participation in the Enterprises through sham "authorships" and serving as

presenting "faculty" at CME events and other honoraria also enhanced the physician participants' professional reputations.

90. The returns on investment ("ROI") in each Defendant's Peer Selling Enterprise were highly favorable. For example, the AbbVie Defendants made the following internal remarks regarding Dr. Ramon Perez's efforts to promote AndroGel off-label: "Dr. Ramon Perez is the most recognized OTL [opinion and thought leader] in the Region. He participated in numerous dinner programs and also was appointed by the AndroGel® Brand Team to develop a National Marketing Program – 'Perez Audio Conference'. He definitely had an impact on the Region's 2003 success."

91. Similar to the Perez Audio Conference was another teleconference program by Dr. Adrian Dobs, Professor of Medicine at John Hopkins, whom the AbbVie Defendants also paid to deliver off-label marketing messages concerning AndroGel. Dr. Dobs received over $15,000 from the AbbVie Defendants in the months of August through November 2013 alone for "Travel and Lodging" and for "Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program." In other words, under-the-radar payments to Dr. Dobs's for her Peer Selling CME lectures funneled by the AbbVie Defendants through its vendor participants are not included.

92. Physician participants were absolutely critical to the success of each Defendant's Peer Selling Enterprise. Indeed, the marketing plans drafted by each Defendant and its vendor participants required their participation. The participation of physicians allowed each Defendant and the vendor participants to disguise promotional events as educational events or consultants' meetings. Moreover, as noted above, each Defendant and the vendor participants knew that

peer-to-peer selling was far more persuasive than traditional drug rep detailing.[1] Primary care physicians are more likely to follow the advice of a Professor of Medicine at Johns Hopkins or another teaching hospital than that of a sales rep. By funneling the payments to the physician participants through the vendor participants, the Peer Selling Enterprises could hide the speakers' financial ties with each Defendant, and the Enterprises were able to mislead physician-listeners into believing that the speakers were not biased and that the events were not promotional. As a result, the vast amounts of money the participating physicians received from one or more of the Defendants, for speaking and other purposes, was largely hidden from the physicians who attended events at which the participating physicians spoke.

93. Physicians who participated in the Peer Selling Enterprise(s), either as speakers or as authors, entered into mutually advantageous contractual relationships with the Defendant(s). The more favorable a physician's statements were, the more he or she could expect to receive in the form of speaker fees, consulting fees, advisory board fees, and research grants. Physicians who refused to deliver the favorable off-label messages that each Defendant wanted were blackballed and would not receive additional payments.

94. The participating physicians knew that minimal scientific evidence supported the use of TRT drugs for the off-label uses and that the type of clinical evidence that existed was insufficient, under the accepted standards in the medical profession, to represent that TRT drugs worked for the unapproved indications.

95. Physician participants worked with, and were retained by, multiple vendor participants. All of the physician participants also had personal relationships with employees of

[1] When a sales representative "details" a physician, often during a call to the physician's office during work hours, the representative delivers to the physician the pharmaceutical company's key selling messages for one or more pharmaceutical products. In most cases, the sales pitch is accompanied by handing out free samples of the product and/or approved materials delivered to the physician, such as sales aids, slides, or branded merchandise such as pens and prescription pads.

each Defendant, and frequently each Defendant recommended specific individual participants for events.

96. Some of the physicians that participated in the AndroGel Peer Selling Enterprise include(d): Glenn Cunningham, MD (Internal Medicine, Baylor Clinic, 6620 Main St., Suite 1375, Houston, TX, 77030), Adrian S. Dobs, MD (The Johns Hopkins Hospital, 600 N. Wolfe St., 1830 Monument Street Room 328, Baltimore, MD 21287), Ken Goldberg, MD (Texas Urology, 541 W. Main St., Suite 150, Lewisville, TX 75057), Larry Lipshultz, MD (Baylor College of Medicine, 6624 Fannin St., Suite 1700, Houston, TX 77030), John Morley, MD (SLUCare Endocrinology, 1034 S. Brentwood Blvd., Saint Louis, MO 63117), Thomas Mulligan, MD (Senior Health Clinic, 303 E Matthews Ave, Suite 202, Jonesboro, AR 72401), Ramon Perez (5305 Gulf Dr., Suite 4, New Port Richey, FL 34652), Harrison Pope, MD (Mclean Hospital- Psychiatry, 115 Mill St, Belmont, MA 02478), Richard F. Spark, MD (Beth Israel Hospital, 148 Chestnut Street, Needham, MA 02492), Ronald Swerdloff, MD (1124 West Carson Street RB-1, Torrance, CA 90502), Christina Wang, MD (General Clinical Research Center, 1124 West Carson St., RB-1, Torrance, CA 90502); Molly M. Shores, MD (1660 S. Columbian Way, MS 358280 (S-182B), Seattle, WA 98108); Abraham Morgentaler, MD (Men's Health Boston, One Brookline Place, Suite 624, Brookline, MA 02445); Shalender Bhasin, MD (70 Albany Street, Boston, MA 02118); Alvin Matsumoto, MD (1660 S. Columbian Way, Seattle, WA 98108); and Peter J. Snyder, MD (University of Pennsylvania Medical Center, 3400 Civic Center Blvd., Philadelphia, PA 19104).

97. Some of the physicians who participated in the Testim Peer Selling Enterprises include(d): Mohit Khera, MD (Urology, Baylor College of Medicine Medical Center, 7200 Cambridge St., Suite 10B, Houston, TX 77030), Larry Lipshultz, MD (Baylor College of

Medicine, 6624 Fannin St., Suite 1700, Houston, TX 77030), Rajib K. Bhattacharya, MD (3901 Rainbow Blvd., Kansas City, KS 66103); Gary Blick, MD (153 E Ave. # 32, Norwalk, CT 06851); Abraham Morgentaler, MD (Men's Health Boston, One Brookline Place, Suite 624, Brookline, MA 02445); Martin Miner, MD (Brown University – Miriam Hospital, 164 Summit Avenue, Providence, RI 02906); Jacob Rajfer, MD (1000 W Carson St, Torrance, CA 90502); Irwin Goldstein, MD (6719 Alvarado Road, Suite 108 San Diego, CA 92120); Jed Kaminetsky, MD (215 Lexington Ave., 20th Floor, New York, NY 10016); Culley C. Carson III, MD, FACS (101 Manning Dr., Chapel Hill, NC 27514); Edward D. Kim, MD (1928 Aloca Hwy, Knoxville, TN 37920); and Ridwan Shabsigh, MD (161 Fort Washington Ave., New York, NY 10032).

98. Some of the physicians who participated in the Axiron Peer Selling Enterprise include(d): Ronald Swerdloff, MD (1124 West Carson Street RB-1, Torrance, CA 90502); Mohit Khera, MD (Urology, Baylor College of Medicine Medical Center, 7200 Cambridge St., Suite 10B, Houston, TX 77030); Irwin Goldstein, MD (6719 Alvarado Road, Suite 108, San Diego, CA 92120); Christina Wang, MD (General Clinical Research Center, 1124 West Carson St., RB-1, Torrance, CA 90502); Isaiah Pittman, MD (3560 S. 4th Street Terre Haute, IN 47802); L Dean Knoll (345 23rd Ave. N. Suite 212, Nashville, TN 37203); Abraham Morgentaler, MD (Men's Health Boston, One Brookline Place, Suite 624, Brookline, MA 02445); Wayne J.G. Hellstrom, MD, FACS (1415 Tulane Ave., New Orleans, Louisiana 70112); Martin Miner, MD (Brown University – Miriam Hospital, 164 Summit Avenue, Providence, RI 02906); Matt. T. Rosenberg, MD (214 N. West Ave., Jackson, MI 49201); Cully C. Carson III, MD, FACS (101 Manning Dr., Chapel Hill, NC 27514); Louis Kuritzky, MD (625 SW 4th Ave., Gainesville, Florida 32601); Jed Kaminetsky, MD (215 Lexington Ave., 20th Floor, New York, NY 10016); Richard Sadovsky, MD (450 Clarkson Ave., Brooklyn, NY 11203); Robert Oberstein, MD (100 Retreat

Ave. #400, Hartford, CT 06106); Shehzad Basaria, MD (670 Albany Street, 2nd Floor, Boston, MA 02118); Pascal Dauphin, MD (3810 Bedford Ave., Nashville, TN 37215); Sandeep Mistry, MD (970 Hesters Crossing Rd. #101, Round Rock, TX 78681); Manish Damani, MD (1718 E. 4th Street #807, Charlotte, NC 28204); Edward D. Kim, MD (1928 Aloca Hwy, Knoxville, TN 37920); Edward Condon, MD (6080 Jericho Turnpike #314, Commack, NY 11725); Adrian S. Dobs, MD (The Johns Hopkins Hospital, 600 N. Wolfe St., 1830 Monument Street Room 328, Baltimore, MD 21287); James Wigand, MD (7001 Jahnke Road, Richmond, VA 23225); Douglas Grier, MD (21822 76th Avenue West, Edmonds, WA 98026); Allen Seftel, MD (3 Cooper Plaza, Camden, NJ 08103); Ridwan Shabsigh, MD (161 Fort Washington Ave., New York, NY 10032).

99. Some of the physicians who participated in the Androderm Peer Selling Enterprise include(d): Jed Kamintesky, MD (215 Lexington Avenue, New York, NY 10016); Abraham Morgentaler, MD (Men's Health Boston, One Brookline Place, Suite 624, Brookline, MA 02445); Herbert Lepor, MD (150 E. 32nd St. New York, NY 10016); Kenneth Kernen, MD (130 Town Center Dr. Troy, MI 48084); Evan Goldfischer, MD (1 Columbia Street, Poughkeepsie, NY 12601); James Bailen, MD (100 E. Market St. Louisville, KY 40202)

100. Some of the physicians who participated in the Fortesta Peer Selling Enterprise include(d): Richard Sadovsky, MD (450 Clarkson Ave., Brooklyn, NY 11203); Allen Seftel, MD (3 Cooper Plaza, Camden, NJ 08103); Adrian S. Dobs, MD (The Johns Hopkins Hospital, 600 N. Wolfe St., 1830 Monument Street Room 328, Baltimore, MD 21287); Andre Guay, MD (1 Essex Center Dr, Peabody, MA 01960); Michael Brennan, MD (301 E Wendover Ave, Greensboro, NC 27401); Ridwan Shabsigh, MD (161 Fort Washington Ave., New York, NY 10032); Wayne J.G. Hellstrom, MD, FACS (1415 Tulane Ave., New Orleans, Louisiana 70112).

101. Plaintiff does not at this time know the identity of all of the physician participants, which likely number in the hundreds.

102. The Defendants' respective Peer Selling Enterprises each sponsored hundreds of events across the country between 2000 and the present. The Plaintiff and the Class Members have only had an opportunity to review the records of a small subgroup of these events. Based on the records reviewed to date, dozens of physician participants received $25,000 or more for participating in the Peer Selling Enterprise activities of one or more TRT drugs for the time period indicated below (not counting travel, food, lodging and entertainment benefits they received for events held at resorts or out of town hotels).

103. In order to implement their respective plans to transform their TRT drug(s) into blockbuster drugs despite a small on-label patient population, each Defendant created separate Peer Selling Enterprises composed of each Defendant, co-promoting firms including those listed above, numerous medical marketing vendors, research institutions and physician societies, and dozens of physician participants, some of whom are listed above and others whose identities will be revealed in discovery. These participants all acted together and under each Defendant's control in promoting the Defendants' respective TRT drug(s) off-label to the healthcare industry, employing numerous tactics with an enormous degree of success.

104. Each Defendant, co-promoters, and the medical marketing firms hosted numerous seminars and events over the course of several years that were falsely represented to be neutral, educational forums. At these events, the roster of physician participants provided misleading and deceptive information to fellow physicians on the off-label uses of TRT drugs(s) (i.e., peer-to-peer marketing). The physician participants were not independent, but received behind-the-scenes coaching and remuneration from each Defendant and/or its vendors, and often used slide

decks and PowerPoint presentations prepared by the marketing teams of each Defendant. Targeted audience members, many of whom were primary care physicians, were not aware that the specialists (including prominent urologists and endocrinologists) speaking to them were in fact delivering, and being paid to deliver, the off-label marketing messages of each Defendant.

105. In addition, the sales force of each Defendant (and of the co-promoting pharmaceutical companies) promoted the Defendant's TRT drug(s) to physicians through "details" or sales calls to physicians' offices. On these sales calls, sales representatives – often using a sales aid and/or sales script developed by each Defendant's marketing team in conjunction with medical marketing vendors – "detail" the physician on the off-label uses of the Defendant's TRT drug(s). In addition, the sales representatives were instructed to deliver to physicians reprints of medical journal articles advocating the off-label use of the Defendant's TRT drug(s), many of which were created pursuant to the Publication Enterprises, and to notify physicians of and ask for their attendance at upcoming CME events and lectures sponsored by Defendants pursuant to the Peer Selling Enterprise. All aspects of each Defendant's Peer Selling Enterprise were mutually reinforcing.

106. Having already caused an increase in prescribing through the fraudulent and illegal marketing efforts, the sales force of each Defendant then engaged P&T Committees and PBMs, and delivered the same false and misleading sales pitches to encourage favorable formulary placements for their TRT drug(s). Once those formulary placements were obtained, each Defendant attempted to "pull through" on the placements by encouraging use of its TRT drug(s) among that particular payor's members.

107. All components of each Defendant's Peer Selling Enterprise were fully integrated and operated under each Defendant's exclusive control.

B. Formation of the Illegal Publication Enterprises

108. In order to execute their respective publication strategies, each Defendant also needed to generate favorable articles about not only the off-label uses of their respective TRT drug(s), but also to expand the definition of hypogonadism to support the blockbuster sales each Defendant hoped to achieve. However, each Defendant's apparent control of this strategy had to be kept to an absolute minimum. Articles had to appear as if they emanated from independent physicians who were investigating each Defendant's TRT drug(s) independently. To perform these tasks each Defendant established a Publication Enterprise, which created "independent" publications. Each of the Defendant's Publication Enterprises was an association in fact of medical marketing companies, participating physicians and each Defendant, for the purpose of promoting off-label uses of the Defendant's TRT drug(s).

109. Each Defendant's publication strategy required publications from independent physicians when in fact no such publications existed. To effectuate the strategy, each Defendant designed study protocols that had the highest chances of generating favorable results for the off-label use of their TRT drug(s). Sufficiently powered studies assessing the safety and tolerability of TRT drugs were avoided, as conceded by Dr. Peter J. Snyder, lead investigator of the Testosterone Trial, a series of seven (7) trials to assess the effects of TRT among elderly men. Even though one of the Testosterone Trial studies was supposed to have assessed cardiovascular risk, Dr. Snyder himself conceded it was "nowhere near large enough to determine any important risk. Not prostate cancer, not heart disease." Instead, Dr. Snyder ruefully explained that the most important function of the studies was the spin that would inevitably be placed upon the results by the TRT manufacturers. The Testosterone Trial is financially underwritten by the AbbVie Defendants.

110. For example, the Executive Chairman of Defendant Acrux, the Australian pharmaceutical company that developed Axiron and then granted Eli Lilly a license to commercialize Axiron in the United States, noted in one November 2013 presentation that "[c]linical trials are being conducted by Lilly … These trials represent significant commitments by Lilly to expanding the therapeutic indications for Axiron." The listed trials included: "A trial for enhanced sex drive and energy levels"; "An ejaculatory dysfunction trial"; "A trial for suboptimal responders to testosterone gels other than Axiron." The accompanying slide deck also listed "[e]xploratory clinical studies" for Alzheimer's and Multiple Sclerosis patients, late stage cancer patients with cachexia, chronic opioid users, renal disease patients, Type II diabetics and obese patients. Since the acknowledged purpose of the Eli Lilly studies was to "expand the therapeutic indications" for Axiron and support a host of off-label uses, no safety studies assessing cardiovascular risk as a primary endpoint appear to be in Eli Lilly's Axiron pipeline.

111. Maintaining absolute control over the respective Publication Enterprises, each Defendant (usually through an internal "Publication Strategy Team" or similar group) hand-picked specialists to be the study "investigators," but these specialists have little input in the study design and which study results could be released to the public. Each Defendant, as part of the Publication Enterprise, then hired non-physician technical writers and vendor participants and used internal employees to create the necessary articles and then paid the specialists to be the articles' purported "authors." This practice is referred to as "ghostwriting." In order to monitor the status of publications, and in order to coordinate and execute the ghostwriting plan, marketing firms were necessary. The role played by the firms in assisting each Defendant in creating publications was very similar to the role played by marketing firms in the coordination of peer-to-peer marketing events, and are vendor participants.

112. Feeding into the Peer Selling Enterprise, once the favorable articles were published, each Defendant distributed so-called "reprints" of these publications by the thousands and required its Peer Enterprise physician participants to discuss these study results at peer influence events as part of the publication strategy, and intentionally misrepresented or fraudulently omitted each Defendant's role in the creation and sponsorship of the publications. Physicians who reviewed these publications were led to believe that the publications were the result of independent, unbiased research of the authors of the articles. They were not made aware of the fact that each Defendant had in fact solicited these articles, that they had paid significant sums of money in various forms to the physician authors to induce them to make favorable statements about Defendants' TRT drugs, and that they had controlled the published content of these articles.

113. Even in cases in which physician-authors drafted the articles themselves, they did so under the same system of direction and control through which each Defendant controlled speaker content. Physicians were promised grants and other gifts if they wrote favorable articles. If a physician attempted to write a negative article, each Defendant would attempt to intervene and have a more favorable draft written. If this failed, each Defendant would do its best to suppress the article or restrict its dissemination. As part of the recruitment process of study "authors" and "investigators," such participating physicians were usually required to sign agreements restricting their ability to discuss the studies or their results. Defendants used these agreements to filter potentially negative study results from entering the medical discourse concerning their TRT drugs.

114. Some physicians participated in the Publication Enterprises by publishing favorable journal articles and letters to the editor about off-label use of the TRT drug(s). Each

Defendant paid large sums of money, often in the form of research grants, to the physician participants in order to publish such articles.

115. In some cases, the participating physicians were not required to perform any research or even write the article. Marketing firms who were financed by a Defendant or internal employees of a Defendant ghostwrote articles under the physician participants' names. Physicians merely had to "lend" their names to the articles, in exchange for a payment, which was usually made by the vendor participant so as to minimize reportable conflicts that might otherwise be disclosed at the end of the resulting article. Authorship on such articles also enhanced the professional reputations of participating physicians.

116. The final method by which a Defendant controlled the stream of published information was through a policy of publishing only favorable results of its own internal trials and suppressing results that were unfavorable. The product of this selective publishing was a corpus of data that inaccurately represented safety profiles of the TRT drugs individually and as a class. For example, Xu *et al.*, conducted a recent meta-analysis of randomized placebo controlled clinical trials for TRT products. *See Testosterone Therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials*, 11 BMC 108 (April 2013). Aside from finding that testosterone increased the risk of cardiovascular-related events by approximately 50%, discussed *infra*, the authors also discovered that "[t]he risk of testosterone therapy was particularly marked in trials not funded by the pharmaceutical industry."

117. Pursuant to the express terms of each Defendant's corporate decisions implementing its Publication Enterprise, all information regarding negative studies funded by each Defendant remains in the sole possession of the Defendant and/or members of the

Defendant's respective Publication Enterprise. Without access to records or the negative studies that were funded and the results of those studies, Plaintiff cannot identify specific negative findings. No Defendant has ever produced the results of these studies to the public or to the Plaintiff and their attorneys.

118. Participating physicians and researchers in all of the Publication Enterprises, who were paid by a Defendant to promote the off-label use of that Defendant's TRT drug(s) through seemingly credible medical literature, authored such articles. Each Defendant and its participating medical vendors proceeded by offering funding and support to participating researchers for studies with protocols designed by each Defendant and with predetermined results favorable to off-label uses of the Defendant's TRT drug(s). Articles were then drafted, sometimes by the researchers with each Defendant exercising a heavy editing hand, and sometimes "ghostwritten" by a Defendant's employees or medical literature vendors, such as Watermeadow Medical, an entity that describes its "scientific publications" services as follows:

> Influential, informative and accurate scientific publication writing underpins all clinical, marketing and sales activities. It's a fundamental way of disseminating product information to key audiences and it's one of Watermeadow's key areas of activity. Our services include developing all types of manuscripts, such as primary manuscripts, secondary manuscripts, review articles, letters, editorials and proceedings supplements, as well as abstracts and posters. We can also provide optimization of publication timing and advice on strategic article submission.

119. Articles such as the ones developed by Watermeadow on behalf of Defendant Endo, as well as other medical communications firms acting on behalf of the other Defendants, masqueraded these predetermined and/or cherry-picked study results as credible science, negative results were sequestered, and the resulting articles were published in prominent medical

journals of national subscribership, such as the Journal of Urology or the American Journal of Medicine, when in fact they were replete with each Defendant's off-label marketing messages.

120. Physicians who participated in the Publication Enterprises, either as speakers or as authors, entered into mutually advantageous relationships with the respective Defendant. The more favorable a physician's statements were, the more he or she could expect to receive in the form of research grants. Physicians who refused to deliver the favorable off-label message that each Defendant wanted were blackballed and would not receive additional payments.

121. The participating physicians knew that minimal scientific evidence supported the use of any of the TRT drugs for the off-label uses and that the type of clinical evidence that existed was insufficient, under the usual standards in the medical profession, to represent that TRT drugs worked for the unapproved indications.

122. Physician participants worked with, and were retained by, multiple vendor participants, and were usually paid for their authorship by the vendor participants to minimize reportable conflicts. The physician participants also had personal relationships with employees of a Defendant, and frequently the Defendant recommended specific individual participants for events.

123. The planning and coordination of the Publication Enterprises described below required extensive use of the wires and mails, including mailing invitations to physicians, booking hotels and plane tickets, arranging meals, scheduling and participating on conference calls, and coordinating the content of TRT drug publications.

124. All components of each Publication Enterprise were fully integrated and operated under each Defendant's exclusive control.

C. Formation of the Illegal DTC Enterprises

125. Although the FDCA prohibits off-label marketing of specific products, it does not similarly regulate marketing materials or advertisements that discuss medical conditions or disease states, generally known as "unbranded promotions." Thus, each Defendant and other TRT manufacturers' DTC advertising redefined and expanded the definition of hypogonadism through unchecked and misleading print, internet, and television advertisements.

126. With the help of their associates, each Defendant engaged in DTC advertising campaigns that fraudulently, misleadingly, and unlawfully concealed and minimized serious health risks associated with the use of TRT drugs, and promoted the drugs as safe and effective for unapproved off-label uses lacking scientific support.

127. Each Defendant's targeted DTC advertising was designed to drive patients to ask their physicians for prescriptions for TRT drugs. Prescribing physicians were thus being told to prescribe TRT drugs by a Defendant, by their peers, by respected thought leaders, and by their patients who were exposed to each Defendant's DTC advertising.

128. Ad campaigns on television, print, and the internet urging men age 45 and over to get screened for low testosterone and consider long-term TRT are everywhere. The ads use macho imagery: cars, sports, powerboats, construction, and racing prominently. Untreated men look moderately overweight in many ads, while treated men appear fit and trim. Some of the information on testosterone replacement on the web targets men with high cholesterol, diabetes, COPD, and asthma, suggesting that testosterone replacement therapy could reverse low libido, a bummed mood, and low energy in men age 45 and over. The catch-phrase "is it low T?" is ubiquitous in the AbbVie Defendants' materials.

129. Third party medical marketing firms were critical to Defendants' respective DTC schemes to promote their TRT drugs off-label from the schemes' respective inceptions. The

marketing plans of each Defendant called for off-label information concerning TRT drugs to be widely disclosed directly to consumers through multiple media channels. These programs were produced with the assistance of third party medical marketing firms, some of which are listed above. Under the direction and control of the Defendant, these firms supplied content and controlled the production of the DTC programs.

130. Among the information each Defendant, the participating vendors and the participating physicians deliberately omitted from the DTC events they sponsored was the following: the complete lack of adequate clinical trial evidence to support TRT drugs' off-label uses; negative clinical trial results that demonstrated that TRT drugs were no more effective than other, less costly, medications; negative evidence that TRT drugs did not work for off-label conditions; information that virtually all publications and studies that allegedly supported TRT drugs' off-label use had been funded by each Defendant, respectively; information that virtually all publications and studies that allegedly supported TRT drugs' off label use had been initiated by each Defendant pursuant to a corporate marketing plan designed to increase off-label sales; information that the participating doctors who were conducting the DTC programs had been paid substantial subsidies to use TRT drugs on their patients for off-label purposes; that the DTC events were neither fair nor balanced and were created to insure the consumers would not hear a fair and balanced examination of TRT drugs for off-label uses; information that the events were not funded, as advertised, by an "unrestricted" grant from each Defendant, respectively, but that the grants were conditioned upon the participating vendors and sponsoring institutions putting on presentations that painted the off-label use of TRT drugs in the most favorable light; and information with respect to dangerous side effects revealed through each Defendant's internal research, adverse event reports, and independent research.

131. Each of the participating vendors was in regular communication with the Defendant. In connection with DTC promotion, the participating vendors coordinated their events to ensure their off-label messages reached the most consumers in the most effective manner.

132. The planning and coordination of all of these events by each Defendant and third party medical marketing firms required extensive use of the wires and mails, including the mailing of information to consumers, airing of commercials on television and/or radio, booking of hotels and airplane tickets, the arrangement of meals, the scheduling of teleconference calls, the development and modification of the tactical plans, and the coordination of the content of the presentations on TRT to be presented at the event.

133. In June 2011, an ad (paid for by Abbott) appeared concerning an event held in New York City's Times Square. The event featured a young race car driver, a race car, and old vintage cars. The ad stated that the race car driver had his testosterone checked, that it was fine, and he was relieved. The clear message was that, if you maintain a high testosterone level, you can still drive fast cars and perform like you did 20 to 40 years ago.

134. One 2011 television ad showed a robust man slamming a laptop shut, walking across the screen, with the bold message: "Stop living life in the shadows." An ad in the *Boston Globe* shows a healthy looking man in his forties, reading: "Has he lost that loving feeling? He may have low testosterone (lowT)." Frequently men are shown with their female partners. The men look distracted and disinterested in sex.

135. In an Axiron television ad dated December 10, 2013 that was created by vendor participant Grey Group and titled "Vacation," the patient and protagonist is a handsome partially greying man with scruffy facial hair. He narrates the following to the listener: "I always say, 'Be

the man with the plan.' But with less energy, moodiness, and low sex drive, I had to do something. I saw my doctor. A blood test showed it was low testosterone not age. We talked about Axiron…." Meanwhile, our silver fox of the silver screen is seen engaging in high speed motor boating, receiving a felicitous glance from his younger wife as he pushes the throttle to fully open. The ad then transitions to our protagonist applying Axiron for his symptom treatment, such as depression and low libido. Defendant Eli Lilly's www.Axiron.com website, under the tab "About Low T," urges patients to talk to their doctors if they experience any one of an expansive set of vaguely defined symptoms ranging from "Depressed mood" to "Erectile dysfunction" to "Decrease in strength."

136. In May 2011, the publication *Pharmaceutical Executive* gave Heartbeat and Auxilium Pharmaceuticals (Testim) top billing for "rich media ads that helped dispel common misunderstandings of low testosterone symptoms and increase awareness of the condition and its treatment, while keeping a sense of humor about the potentially sensitive medical issue." The unbranded ads were accompanied by the www.lowtfacts.com website and directed users to additional information on symptoms and treatment.

137. Some low testosterone awareness ads on the internet had links to the American Diabetes Association ("ADA"), implying that ADA must have espoused the point of view that diabetes is associated with low libido, low energy, and low testosterone; hence, screening for low testosterone in men with diabetes is sensible and safe. However, such links have since been removed, perhaps because the implication that the ADA has guidelines on testosterone screening for men with diabetes was misleading.

138. In or about 2009, Solvay deployed a multi-channel fraudulent DTC print and television low testosterone campaign with the platform www.IsItLowT.com. The 30-second

television spot showed a man who missed his old self – his shadow – having fun golfing and disco dancing. The call-to-action for the advertisement was to go online to learn more, accompanied by unbranded DTC ads that call out symptoms or offer a quick LowT quiz. In reviewing the DTC campaign, the company Medical Marketing & Media ("MM&M") stated that "[t]his campaign works because it leverages a bit of mystery and intrigue … If AndroGel can get rid of grumpy old men, we'll all be dancing under the disco ball." MM&M understood the AbbVie Defendants to be promoting AndroGel as an anti-aging and anti-depression medication.

139. One of Defendant AbbVie's marketing initiatives was the "Drive for Five" campaign, which urges men to know their testosterone (T) levels, in addition to lipid, BP, blood sugar and PSA numbers. On the website (http://www.driveforfive.com; "Men's Health | Learn about 5 risks to men's health") is an animated "gear box" that shifts from high cholesterol (first gear) to high blood pressure (second gear) to high blood sugar (third gear) to high PSA (fourth gear) and, finally, to low testosterone (fifth gear). AbbVie's "Drive for Five" DTC ad campaign declares that there are five major risks to male health: high cholesterol, high blood pressure, high blood sugar, high prostate-specific antigens (PSA) levels, and—you guessed it—low testosterone levels. The clear message is that T level is as crucial, or life threatening, as possible hypertension or diabetes.

140. Each Defendant hoped that its DTC campaign would cause patients to wonder whether they could benefit from the TRT drug(s) in question, and to approach their physician concerning treatment. As noted in an AndroGel internal document, the sales force wanted to engage in "Screening Programs to take Advantage of Direct to Consumer Campaign." Once the patient expressed a willingness to be treated with his physician, each Defendant's Peer Selling and Publication efforts were expected to take over.

141. Dr. Adriane Fugh-Berman has been outspoken in the criticism of Low T DTC advertising. In September 2013 in a Chicago Tribune editorial, Dr. Fugh-Berman and PharmedOut project manager Nicole Dubowitz explained how vague suggestions of a loss of manliness have turned into billion dollar sales for testosterone drug peddlers. They explain that through questionnaires, such as the ADAM questionnaire discussed in detail elsewhere, on sites like Auxilium's IsItLowT.com and the AbbVie Defendants' DriveForFive.com, and the over expansive symptoms list on Lilly's Axiron website, it is hard for any man not to determine he must be suffering from low testosterone. While the commercials often claim "it is a number," suggesting a definitive level of testosterone that indicates whether you have low T or you do not, it is simply not that straightforward. As the editorial notes:

> The symptoms are so common and vague, it's a rare person who would avoid self-diagnosing Low T after taking the quiz at IsItLowT.com. The site is sponsored by AbbVie (formerly part of Abbott Laboratories), manufacturer of best-selling testosterone treatment AndroGel. If you're bored, stressed or aging normally, you probably have Low T symptoms: grumpiness, less energy, lower libido and 'falling asleep after dinner.' Even if you feel fine, you may still qualify for treatment. AbbVie's other website, DriveForFive.com, describes five risks to men's health: high cholesterol, high blood pressure, high blood sugar, high PSA levels and — can you guess — low testosterone.

142. In 2010, the Endocrine Society warned that such self-reporting quizzes show little indication of providing useful evidence of a problem. Testosterone treatments were only approved by the FDA for confirmed testosterone deficiency seen in conjunction with an associated medical condition, such as failure of the testicles to produce testosterone due to genetic problems or chemotherapy.

143. This has not stopped each Defendant from inundating men in the U.S. with DTC commercials showing fit men with graying hair (colloquially known as "silver foxes") lifting

heavy objects, jogging down country roads, or making eyes at their (typically much younger) wives. The tactics have worked. Each Defendant's disease mongering increased testosterone prescriptions by a factor of five between 2002 and the present. Defendants themselves openly discuss the success of their DTC programs. As stated by one market research firm, "The ramp-up of [TRT drug] promotional activity is clearly having its desired effect. According to Encuity's *TreatmentAnswers*™ audit, over the course of the last five years, the TRT market has seen dramatic growth in patient visits, up 55% from 1.2 million in 2009 to 1.9 million in 2013." The vast majority of these patients were likely exposed to Defendants' DTC advertising prior to visiting their physician.

144. For example, Acrux reported the following concerning Defendant Lilly's Axiron DTC efforts:

> Lilly's effective use of direct to consumer ('DTC') marketing has been instrumental in building and maintaining market share. During the period in which the Axiron sales force was being restructured, Axiron's market share was maintained by the DTC campaign run by Lilly. Given the effectiveness of DTC advertising in building Axiron's market share to date, we anticipate Lilly will continue to this as a key plank in their overall market development platform.

145. Unfortunately, amid this drive to generate blockbuster medications to improve their bottom lines, each Defendant has failed to provide adequate warnings about the heart risks associated with TRT drugs.

146. All components of each Defendant's DTC Enterprise were fully integrated and operated under each Defendant's exclusive control.

VI. THE ABBVIE DEFENDANTS' FRAUDULENT MARKETING OF ANDROGEL

147. Hypogonadism has been understood for many decades in the medical community to be a rare condition occurring in men across all age groups associated with a deficiency or

absence of endogenous testosterone. The diagnosis of hypogonadism in adult males involves a comprehensive history and physical examination in addition to laboratory tests for levels of testosterone and gonadotropins, and possible further testing to determine the cause.

148. Ever thirsty for expanded sales, over the years the AbbVie Defendants adopted a laundry list of other off-label promotions, promoting AndroGel for "wasting" in HIV and AIDS patients, women, methadone and other opioid users, diabetics and those with "metabolic syndrome" (i.e., obesity). By 2006, AndroGel had grown to be Solvay's top-selling pharmaceutical product, with U.S. sales of over $300 million. AndroGel became Solvay's top-selling drug and the chief asset on sale when Abbott Laboratories bought the company in early 2010. According to publicly-released IMS data, even as recently as the twelve-month period from June 30, 2008 to June 30, 2009, the testosterone replacement drug class increased sales by twenty-five percent, to over $840 million, with AndroGel leading the way. AndroGel sales alone comfortably topped $1 billion in 2012 and 2013.

A. The AndroGel Peer Selling Enterprise

149. Beginning shortly after AndroGel was launched in 2000, the AbbVie Defendants and their associates unleashed a barrage of branded Peer Selling promotions upon potential prescribing physicians from all angles. The AbbVie Defendants' sales representatives detailed physicians on off-label uses, using sales materials and scripts specifically created by AbbVie marketing teams along with medical marketing vendors and distributing reprints of articles created pursuant to the AndroGel Peer Selling and Publication Enterprises that either explicitly promoted the off-label use of AndroGel or grossly exaggerated the hypogonadism prevalence figures as an implicit message that physicians should use AndroGel off-label.

150. Influential physician specialists associated with the AndroGel Peer Selling Enterprise traveled around the country delivering what the AbbVie Defendants described as "peer influence" lectures to other physicians, instructing them to prescribe AndroGel to middle-aged men with age-appropriate testosterone levels (and sometimes women), patients with HIV/AIDS, diabetic patients, patients with erectile dysfunction, osteoporosis patients, patients with clinical depression or who were just "grumpy" according to one screening questionnaire, and as a pain medication.

151. At one point AndroGel brand managers informed the sales force that, according to Peer Selling Enterprise-participating physicians on its "Andropause task force" (the full membership of which will be learned in discovery), up to 20 million men might qualify as hypogonadal, if a "free testosterone" test, rather than a more basic total testosterone test, were used. As field sales representatives ("FSRs") were instructed in one sales planning document, the most important "Key Brand strategy" was to "[s]ell hypogonadism first; then sell AndroGel®[.]" In other words, "[t]he AndroGel® sell came after the physician had a clear education and appreciation of the disease state." Of course, the "education" the AbbVie Defendants and their associates hoped to impart was based on facts largely fabricated in order to sell more AndroGel.

152. By 2006, the AbbVie Defendants' internal marketing presentations were reporting that the average length of time patients spent on AndroGel was by then only four months. Less than seventeen percent (17%) of male patients were still on treatment after a year (including re-starts), statistics which are highly suggestive of off-label use, as true hypogonadism requires sustained, long-term use. Less concerned with the off-label implications and more so with the lost revenue associated with patient non-compliance, the AbbVie Defendants and their associates

introduced programs to increase patients' persistence with AndroGel. One such program was an "AndroGel® Loyal-T Visa® Card" to fulfill the "2005 Strategic Objective of increasing patient compliance and persistency."

153. A key part of the AndroGel Peer Selling Enterprise was buying the influence of prominent doctors and medical researchers. These influential health care professionals would then disseminate a screening tool, the Androgen Deficiency in the Aging Male ("ADAM") questionnaire, which was not designed to detect the on-label condition of hypogonadism, but was rather a biased series of largely subjective questions designed to lead inevitably to answers suggestive of Andropause, and then either a testosterone test and/or an AndroGel prescription.

154. The ADAM questionnaire became a central tool for the Peering Selling and DTC Enterprises. The AbbVie Defendants' sales force was instructed to emphasize "Screening, Screening, Screening…" on sales calls and a "Metric" for the patient screening tactic was simply "# of programs and # of patients screened[.]"

155. Dr. John Morley, the author of the ADAM questionnaire (which was later re-branded as the "Is It Low T? Quiz" and which is still available on multiple of the AbbVie Defendants' websites), recounted that he was asked in the early 2000's by a Dutch pharmaceutical company, Organon BioSciences, to come up with a screening questionnaire covering symptoms common to older men with lower testosterone. The ADAM questionnaire became a central feature of Defendants' and other TRT manufacturers' unbranded aspect of the AndroGel Peer Selling Enterprise to inflate hypogonadism prevalence numbers. According to Dr. Morley, his instructions were: "Don't make it too long and make it somewhat sexy." As Dr. Morley recalled, he drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper, and then gave them to his secretary the next day to type up. When

asked his opinion of the questionnaire years later, Dr. Morley responded: "I have no trouble calling it a crappy questionnaire." And yet this "crappy questionnaire" is a central feature of the AndroGel Peer Selling and DTC Enterprises. As emphasized to the AbbVie Defendants' sales force in one internal marketing strategy document: "ADAM must be left and sold with each AndroGel target."

156. Not surprisingly, Dr. Morley and his institution, St. Louis University, have been beneficiaries of the AbbVie Defendants' largesse and have partnered in promoting AndroGel for years afterward for the treatment of Andropause through a national continuing medical education ("CME") Grand Rounds series, and other programs. The Grand Rounds involved Solvay speaker events held in every region of the U.S., and dozens of speakers, including physician participants Drs. Ken Goldberg, Molly Shores, Glenn Cunningham and Larry Lipschultz. Physician participant Dr. Morley has since received Solvay funds to study testosterone and renal failure as well as membership on Solvay's and Unimed's speaker bureaus.

157. The AbbVie Defendants instructed sales representatives to talk to doctors about symptoms and "low testosterone," or even better, "low T" (a term Dr. Morgentaler proudly claims to have coined) rather than "hypogonadism." Importantly, "low T" is not synonymous with "hypogonadism." Accordingly, an HIV off-label sales aid first introduced in January 2002, is entitled, "You're managing his HIV – Help him manage his low T." Similarly, a mid-2002 homework assignment from a Midwest Region sales representative suggested the close, "[w]hen a patient comes in and asks for Viagra, will you first screen for low T?" By supporting the prevalence figures it had manufactured with these tactics and misleading language, the AbbVie Defendants and other TRT manufacturers were able to sell the notion that male hypogonadism was an American epidemic to physicians, patients, Plaintiff and the Class Members.

158. The success of AndroGel hinged on off-label promotion, but because the AbbVie Defendants had to maintain plausible deniability for such promotion, it was difficult to rely entirely on its sales force to promote AndroGel off-label.

159. Much of the burden of the off-label promotion was reserved for physician speakers paid by the AbbVie Defendants, who delivered presentations to other doctors that frequently advocated off-label AndroGel use for any of the off-label uses described above. Sales representatives and professional services associates (sometimes called "medical liaisons" or "medical science liaisons" at other companies) played an integral role in disseminating off-label information through physician speakers.

160. According to an internal AbbVie Defendant document, the number one "Tactic" in the AbbVie Defendants' campaign to "[l]ink hypogonadism to other chronic disease states" was to "Develop local OTLs [opinion and thought leaders] in each territory." The shorthand description of the participating physician's role in the Peer Selling Enterprises was to "[p]rovide literature [often ghostwritten as part of the Publication Enterprise] to verify and cite other chronic conditions to low T." The "Metric" for success was "[m]essages agreed upon by OTL and confirmation of" the physician's efforts to promote off-label usage of AndroGel at such events. The AbbVie Defendants ensured that the participating physicians were properly indoctrinated through "ML [medical liaison] involvement in OTL development for each territory." The ML's were employees of the AbbVie Defendants who were often trained in pharmacology or who held other advanced science degrees; these ML's developed slide kits for use by the participating speaker physicians to ensure that the favorable publications developed pursuant to the Publication Enterprise were known and used by the participating physicians.

161. The AbbVie Defendants referred to such interactions as "peer influence events." The AbbVie Defendants succinctly explained the objective: "Utilize our URO/ENDO Advocates to convince PC MDs of safety and tolerability of AndroGel …." In other words, urologists and endocrinologists represented the thought leaders in the field, and primary care physicians are typically heavily influenced by these specialists. The AbbVie Defendants were thus regularly "developing more OTLs" and utilizing them to exert "peer influence" on primary care physicians to convince them of the safety, efficacy, and usefulness of AndroGel for off-label uses.

a. ***CME Events***

162. CMEs delivered by physicians were a frequently-used medium for off-label Peer Selling messages. The AbbVie Defendants sponsored and improperly influenced live CMEs relating to off-label topics, often given in conjunction with a paid-for lunch or dinner.

163. For example, in 2002, the AbbVie Defendants paid $26,000 to the American Geriatrics Society, then affiliated with Dr. Thomas Mulligan, author of the HIM study. A ROI form reveals that the money was for a single off-label CME Dinner in conjunction with Virginia Commonwealth University entitled, "Menopause and Andropause: What Do You Know and What Should We Do in 2002," at which Dr. Mulligan served as a paid speaker on "age-associated hypogonadism" and "subsets of the male population (other than those that fall under the current guidelines of being hypogonadal) that can benefit from testosterone replacement."

164. The AbbVie Defendants' sales representatives not only helped host CMEs, but frequently provided doctors with CME credit during calls by playing pre-recorded CMEs, typically on an off-label topic, and typically influenced by the AbbVie Defendants and/or their associates with regard to content and speaker choice, while feeding lunch to the doctor and the doctor's staff. AndroGel Peer Selling associates commonly handled the application for CME

credit on behalf of doctors at these Lunch n' Learns, even filling out required quizzes on the contents of the CME.

165. In October 2005, the AbbVie Defendants and/or their associates provided an educational grant to the University of Wisconsin for a CME lecture series delivered by Drs. Ronald Swerdloff, Christina Wang, and Richard Spark on "Testosterone Deficiency in Men." The lectures touted the benefits of testosterone and downplayed the risks. Solvay AndroGel Speaker Bureau members delivered all three lectures, two of which focused on aging men, the third on diabetes. The lectures were later packaged as CME articles. In conjunction with publication of those articles, Solvay paid about $1 million to fund University of Wisconsin-sponsored doctor education in 2005, 2006 and 2007 such as dinner meetings around the country and newsletters designed to reach more than 50,000 physicians. The University of Wisconsin's CME program has been the subject of intense criticism. One article, which focused on UW's AndroGel CME articles, stated that the CME articles "read more like promotions than rigorous research, touting the benefits of testosterone and downplaying the risks." John Fauber, *Side Effects -- Are Doctors' Loyalties Divided? -- UW Tied To Male Hormone Marketing Testosterone Prescriptions Soar Despite Weak Research*, Milwaukee Journal Sentinel, August 8, 2009, http://www.jsonline.com/news/health/52802117.html (last checked on September 22, 2014). The article further averred that "UW was an active participant in the testosterone surge" and "directly received about $115,000" from the AbbVie Defendants. Solvay hired for-profit medical education consultant Dowden Health Media not only to organize the events, but to participate in preparing the content of the lectures.

166. Oftentimes, CMEs were delivered on leave-behind CD-ROMs or by means of telephonic audio conferences. The AbbVie Defendants referred to this method as "Instant Recall

Audiotext" ("IRA") or "distance learning." For example, over 4,500 physicians listened in 2002 and 2003 to an AndroGel talk entitled, "The Aging Male: New Advances in the Treatment of Hypogonadism," given by Solvay-funded speaker and researcher Adrian S. Dobs. The producer of the IRA program was INCE. Solvay controlled the content of INCE programs, down to the placement of a comma in a presentation. Solvay's Regulatory Department, for instance, demanded revisions to a similar AndroGel CME to be delivered via CD-ROMs in 2003, including, as relayed by AndroGel's associate product manager, the deletion of the phrase, "In the aging male," masking the presentation's Andropause theme.

167. The AbbVie Defendants often required sales representatives to meet quotas regarding these in-office CMEs. Managers generally kept track of and held out as a job accountability the number of IRAs or similar programs that sales representatives completed.

b. ***Promotional Speakers***

168. The AbbVie Defendants conveyed off-label messages through promotional speakers as well. The AbbVie Defendants' promotional speakers included, among others, otherwise inaccessible high prescribers whom sales representatives chose as regional or national speakers mainly in order to "build relationships." These relationships included an implicit consideration element, discussed in more detail below. In exchange for being paid substantial sums of money to give lectures using slide decks supplied by the AbbVie Defendants promoting the off-label use of AndroGel, these high-prescribing physicians understood that they were to write large volumes of AndroGel prescriptions to their patients.

169. The AbbVie Defendants' sales representatives often drove these speakers to their lectures, and/or attended to make sure that the speaker was delivering the appropriate key selling points regarding the off-label use of AndroGel. If the physician did not adequately promote

AndroGel at these speaking events, he/she would be dropped from the AbbVie Defendants' speaker rosters.

170. In addition, the AbbVie Defendants' sales representatives supplied these high-prescribing physicians with large amounts of free samples as part of this arrangement. These samples were given out by the physicians to their non-hypogonadal patients in order to support the off-label use of AndroGel.

171. There were also "coachable" regional doctors recruited by sales representatives, some of whom became national speakers for the AbbVie Defendants. These speakers were often local specialists, such as urologists, hired to speak to primary care physicians to tout the benefits of AndroGel to primary care physicians.

172. The sales force and professional services associates (PSAs) from Solvay's Professional Services Department typically developed promotional speakers. PSAs were what many pharmaceutical companies called medical liaisons. They often had degrees – masters of science, or registered pharmacists, or PhD's – and they had supposed impunity to provide off-label materials to physicians, including slide decks to be used as speaking events. Their job was to groom, and to provide all the off-label research and promotional messages for, physician speakers whom the AbbVie Defendants were developing.

173. In developing a speaker, PSAs would go to Marketing and ask questions like, "if you could have Dr. X Speaker say anything you wanted, what would it be?" The more coachable of the speakers developed by PSAs were used more frequently and rose to national ranks.

174. The AbbVie Defendants referred to the most influential physicians as national OTLs. OTLs could either be groomed physicians who started as regional speakers and who proved to be successful in touting AndroGel's off-label promotional messages, or they could be

already prominent physicians, often researchers with long publication lists, whose support lent credibility to the AbbVie Defendants' off-label claims about AndroGel. These OTLs spoke on a national circuit, and sometimes lectured to the sales force at national meetings.

175. Particularly effective speakers sometimes traveled throughout a territory with a representative on a circuit of different speaking engagements. Typically, handouts and a meal were included.

176. For example, Dr. Ramon Perez was a local speaker who became a popular regional traveling speaker for the AbbVie Defendants, eventually giving nationwide CME lectures, and speaking on AndroGel and expanded definitions of hypogonadism, as described above. Other regional AndroGel physician speakers have included Dr. Glenn Cunningham, who spoke on AndroGel and diabetes.

c. ***AndroGel Peer Selling Message to Physicians***

177. Sales representatives acted as the AbbVie Defendants' front line in delivering off-label messages to physicians about all the drugs at issue here. The AbbVie Defendants' sales forces are divided into various specialty groups, including primary care. Primary care sales representatives are typically responsible for marketing several drugs at the same time. The AbbVie Defendants required sales representatives to make frequent calls on doctors targeted by management using detailed prescribing data available commercially.

178. The goal was to identify high prescribers within a product's drug class (or for potential off-label uses) and high potential prescribers of the drug in addition to those already heavily prescribing the drug. Physicians targeted by the AbbVie Defendants include primary care doctors, gerontologists, endocrinologists, urologists, psychiatrists, and others, especially those prescribing high numbers of hormones, Viagra, or Cialis. The same high-level managers and

executives at Solvay Pharmaceuticals' Atlanta headquarters (and presently at the AbbVie Defendants' Illinois headquarters) who shaped the off-label schemes at issue assigned targeted doctor lists contained in electronic "DART" data (prescribing activity data purchased from an outside vendor) to districts and particular representatives on a semi-annual basis.

179. The AbbVie Defendants often reserved the most blatant off-label communications with its sales force for closed-door sessions with smaller groups at regional or national meetings.

180. The AbbVie Defendants sales representatives, professional service associates, district managers, and regional managers, as well as the brand or marketing team, were involved in the off-label marketing campaign for AndroGel and in the execution of the Peer Selling, Publication, and DTC Enterprises, as the essential sales needed for AndroGel to become a commercial success were off-label.

d. ***Marketing AndroGel from the Outset for the Treatment of "Andropause"***

181. The AbbVie Defendants had planned to market AndroGel off-label long before the FDA even approved AndroGel for hypogonadism.

182. At least three (3) years before AndroGel gained FDA approval, Solvay's predecessor, Unimed Pharmaceuticals, Inc., received a letter from the FDA Division of Drug Marketing, Advertising and Communications ("DDMAC") pertaining to a March 31, 1997 news release for AndroGel. Aside from promoting AndroGel as safe and effective prior to FDA approval and while still under investigation, forbidden by 21 C.F.R. § 312.7, the news release also listed as a potential use "treatment of geriatric hypogonadism in elderly men and the treatment for postmenopausal women," indications that were not even under consideration by the FDA at the time.

183. Ignoring the FDA's warning not to promote AndroGel for off-label uses, the AbbVie Defendants' AndroGel launch letter explicitly promoted the product for a host of off-label uses. As stated in the July 18, 2000 launch letter addressed to doctors and P&T Committees, "AndroGel® … resulted in significant increases over time in total body mass, significant improvement in libido and increased degree of penile erection (as determined by patient questionnaire). Additionally, AndroGel® … produced positive effects on mood and fatigue. Bone mineral density in both the hip and spine increased significantly …." As demonstrated, even before approval and on the first launch day, there was a plan in place to market AndroGel off-label as a remedy for any number of off-label ailments.

184. The AbbVie Defendants promoted an expanded definition of hypogonadism to create the figures necessary to support the supposedly vast silent epidemic delineated in the Peer Selling Enterprise. The AbbVie Defendants have marketed (and continue to market) AndroGel for "Andropause," a dubious medical condition for which the FDA has never approved the drug. The AbbVie Defendants have promoted this off-label use despite admonitions from the FDA in early 2000 that Andropause, or "age-related hypogonadism" is *not* an approved indication. Specifically, a pre-launch letter from DDMAC dated April 12, 2000 to Unimed objected to the following phrases in a proposed sales aid: "'Age-associated' hypogonadal causes" and "Greater than 60 percent of men over 65 have free testosterone levels below normal values of men aged 30-35." DDMAC commented:

> Claims and representation that suggest that AndroGel is indicated for men with "age-associated" hypogonadism or "Andropause" are misleading. AndroGel is indicated in males with primary hypogonadism or hypogonadotropic hypogonadism.

185. The AbbVie Defendants well understood the prohibition, and its regulatory department often disguised promotion for "age-related" hypogonadism, by removing references

to "older patients" from draft sales aids, and changing phrases like "[i]s it age, or is it hypogonadism," to "[i]s it part of life or is it hypogonadism?" It also explains the virtual disappearance of the term "hypogonadism" from the AbbVie Defendants' communications, instead replaced by the much broader term "Low T." As described below, however, the AbbVie Defendants have targeted (and continue to target) older men experiencing symptoms of aging and men with age-appropriate testosterone levels.

186. While the AndroGel Peer Selling Enterprise had its Andropause messaging roots established even before the launch, AndroGel's sales exploded after the company focused more sharply on "educating" doctors about the Andropause condition its marketing vendors had created.

187. In 2000, the AbbVie Defendants laid the foundation for sales by scheming with influential specialists to support an expanded need for testosterone supplementation. An outside consultant, EDU-Medical Management, Inc., an associate in the AndroGel Peer Selling Enterprise, issued a report to Unimed/Solvay in 2001 that stated: "It is understood, AndroGel cannot be promoted for off-label uses by Unimed Pharmaceuticals," with the apparent plan to take on that off-label promotion on its client's behalf. Its first "Medical Education Objective" was to "Create educational vehicles to identify age-related hypogonadism and showcase AndroGel® as the appropriate/ideal treatment option."

188. As part of that effort, Peer Selling vendor participant EDU-Medical Management, Inc. declared in the same report that Solvay had already developed its own "consensus guidelines" for testosterone replacement therapy and planned to bring them to the Endocrine Society's 2001 Andropause Consensus meetings with the goal "to have them endorsed" by this supposedly independent group of specialists. Defendants succeeded, thanks in no small part to

pouring funds into the society's treasury and its board members' wallets. The Endocrine Society accepted the offer, along with an "unrestricted educational grant" in the amount of $139,482 to be used to produce a CME video entitled "Andropause Consensus 2000: Advances in Testosterone Replacement Therapy" as well as a CME entitled "Aging Men and Women: Does Sex Steroid Therapy Improve Quality [of Life]." Consensus guidelines and other best practices materials promulgated or endorsed by physician societies, such as the Endocrine Society, have been routinely provided to P&T Committees and PBMs in order to influence them when evaluating whether and how to place pharmaceutical products on their formularies.

189. The AbbVie Defendants held numerous physician events, which focused on Andropause messaging. For instance, later in 2001, Solvay held "Physician Speaker Facilitator Workshops" to train over 300 regional urologists and endocrinologists to speak on the "importance of TRT and the critical role of Andropause."

190. By late 2001, the AbbVie Defendants were ready to capitalize more fully on their "educational" efforts. The AbbVie Defendants directed the sales force through flyers and at POA meetings that the goal for 2002 was "to grow the market.... Instead of going after a bigger piece of the pie, we need to make a bigger pie." Specifically, the AbbVie Defendants' internal Marketing plans aimed to expand the testosterone market by a whopping 36.5 percent. Primary care physicians were to be targeted as the main source for such growth, as these non-specialists were more likely to believe the AndroGel "stories" they were being told by the AbbVie Defendants' sales force and physician participants. The rationale underlying the primary care focus was explained as:

> The Testosterone Market continues to grow in the Primary Care Sector, even though growth from Specialists (Endo, Uro's) has leveled off. Physicians are screening more often for Low Testosterone, but they continue to receive push-back from

> specialists who are not comfortable prescribing Testosterone for symptoms of Low T or Low-Normal Levels.

191. The AbbVie Defendants and their associates made the linguistic move to "low T" at this time as well in order to support the Peer Selling Enterprise. "Peer influence" efforts were redoubled in 2002 to assist in the primary care sector. Sales from 2001 had been $115.8 million. By November of 2002, annual sales had already reached $164 million, and by the end of 2002 sales reached $188 million.

192. The "education" that the AbbVie Defendants and the Peer Selling Enterprise associates provided to physicians and consumers concerned the supposed existence of the invented disease state Andropause and widespread need for hormone replacement therapy in men. The AbbVie Defendants noted the overall decline in testosterone among men as they reach old age and claimed that such a decline was not a "normal" part of aging but a disorder affecting strength, well-being, cognitive function, mood, sexual function, and other attributes, sometimes disproportionately or acutely, not unlike menopause in women. In early 2002, the AbbVie Defendants instructed the sales force to stop discussing TRT, and use the term "HRT" —"*His* replacement therapy," an allusion to hormone replacement therapy for women.

193. Importantly, in identifying those supposedly suffering from Andropause, the AbbVie Defendants applied the same normal range for testosterone to octogenarians that they did to twenty-year-olds (despite the fact that testosterone levels decline naturally in men as they age). The AbbVie Defendants further used (and still use) the over-inclusive ADAM screening questionnaire described above to persuade "andropausal" men that they need AndroGel. As the long title of the questionnaire indicates, it was never designed to identify male hypogonadism. It was designed to identify "androgen deficiency in aging men" – in other words, Andropause or "age-associated" hypogonadism.

194. The term "Andropause" itself was not only absent from AndroGel's label, but its existence as a recognized medical condition is questionable. It has never been listed in any drug compendium. The FDA has never approved a drug for treating Andropause. The notion that sex hormones maintain or improve a person's health into old age has turned out to be a flawed one as applied to women, most famously with regard to the World Health Organization's estrogen replacement study, which was aborted early because of the prevalence of dangerous adverse effects. As discussed below with regard to the recent safety revelations concerning TRT drug therapy, the use of testosterone replacement therapy in men appears headed for the same fate. The facile way in which the AbbVie Defendants have urged (and continue to urge) the same theory for aging men may endanger men's health in similar ways. In particular, steroid and testosterone use are associated with prostate or testicular cancer, increased cardiovascular adverse events, and may cause the body to reduce its own manufacture of testosterone, perhaps permanently.

195. Coaxing physicians into screening patients through the ADAM questionnaire or otherwise was crucial to the AbbVie Defendants' Peer Selling Enterprise, because false positive results were frequent, and led either directly to an AndroGel prescription, or to a testosterone test. As reported in the 2013 JAMA article *supra*, one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription, such as for AndroGel. The ADAM questionnaire created as part of the Peer Selling Enterprise influenced this high number of AndroGel prescriptions written with no testing of patients' testosterone levels. Indeed, testing strategies were central to the marketing of AndroGel, as the AbbVie Defendants exploited the notorious unreliability of such tests in hopes of false positives. With older men, the AbbVie Defendants suggested, a free testosterone test was superior to a total testosterone test, the

standard test, and particularly, if a total testosterone test came back in the low-normal range or the borderline hypogonadal range, a free testosterone test should be performed as well.

196. Relying on these strategies of heavy "screening and testing" allowed the AbbVie Defendants to identify far more patients beyond those suffering from AndroGel's on-label indication. It segued easily into the promotion of AndroGel to aging men with normal testosterone levels and men with "age-associated hypogonadism," despite the FDA's warnings.

197. Sales training materials circulated in July 2001 and adopted in the Mid-Atlantic, South, and Southwest districts, for instance, reflecting the company's nationwide marketing strategy, proposed that testosterone supplementation was necessary for the well-being of many aging men with normal testosterone levels. Those materials, authored by Tom Dovel, a Mid-Atlantic Region district manager, claimed that aging men need AndroGel when their testosterone level suddenly dips, even if it remains within the normal range. "We can help write a new paradigm. One that captures both the andropausal male, as well as the hypogonadal male," the materials promised.

198. Perhaps, the materials posited, a man in his fifties was accustomed to a testosterone level of 1000 mg/dL, but experienced a sudden drop in testosterone that nevertheless remained in the normal range. Training materials urged that to *feel* "normal," that man needed to boost his testosterone levels. Representatives were told to ask doctors to look at how far a man was "*from the top of the normal range*, rather than how close he is to *the bottom of it*." As long as AndroGel treatment would not boost a patient's testosterone levels above the upper reaches of normal range, he was a candidate for "low T" treatment.

199. Accordingly, in December 2001, Tim Hatke, AndroGel Product Manager, directed sales representatives to deliver to physicians a CME video entitled "Andropause

Consensus 2000: Advances in Testosterone Replacement Therapy" at the end of sales calls. The video covered supposed Andropause symptoms including decreased sexual desire, fatigue, and osteoporosis, as well as depression, and advocated the use of free testosterone testing, which would yield a larger number of positive results than would total testosterone testing. The Endocrine Society, whose own coffers and members were recipients of Defendants' grants or fees, created the video. A written CME package was also created, containing eleven articles, eight of which bear titles including "Andropause" or other references to aging. Later, in January 2002, the AbbVie Defendants disseminated the Endocrine Society-endorsed consensus guidelines that the AbbVie Defendants' vendor drafted and proposed, which unsurprisingly recommended a broader use of "testosterone therapy."

200. By 2004, Solvay district managers spoke and wrote openly to their supervisors and their sales representatives about changing doctors' perception about what is a "normal" T level. For example, one Mid POA II and AndroGel Pump Launch handout for sales representatives in 2004 that stated under "AndroGel® Core Message Strategy":

> Finally, as we discussed, find ways to change the doctor's perception of what's a 'Normal' T level, by discussing the AACE Guidelines and algorithm, and using Specialist peer influence, along with giving full disclosure of our indications and PI information.

201. These and similar statements made by specialist thought leader physicians and researchers, as well as reputable sources such as the Endocrine Society, advocating more expansive testosterone use were relied upon by Plaintiff and the Class Members in deciding whether and how to include AndroGel on their formularies.

202. The AbbVie Defendants' speakers increasingly promoted AndroGel for Andropause during this period. At a National Business Meeting in Las Vegas in January 2002,

Dr. Larry Lipshultz of Houston, Texas, lectured the sales force on Andropause. Handwritten notes from that lecture reveal that he suggested a "focus on aging" in marketing, noting the aging population of baby boomers, and advocated treating patients with borderline or normal testosterone with AndroGel based on symptoms, "not lab values." In February, the Pittsburgh District sponsored two speakers at a West Virginia DO conference in Charleston, West Virginia. At that conference, a presentation titled "Andropause and the Role of AndroGel" was given to around 120 physicians by a Solvay-paid doctor. Also in 2002, 4,500 doctors listened to Solvay's call-in audio-teleconference entitled, "The Aging Male: New Advances in the Treatment of Hypogonadism," presented by Dr. Adrian S. Dobs, a physician participant in the Peer Selling Enterprise.

203. Speakers like Dr. Ramon Perez first catapulted to nationwide speaker status in 2003 by pressing the envelope regarding "normal" testosterone levels. Sales representative Stephanie Boeke's summary of a Dr. Perez presentation to thirteen professionals on May 26, 2004 in San Antonio, Texas, states he pushed the idea that any testosterone level under 500 ng/dL should be treated, even though testosterone levels above 298 ng/dL were deemed normal in studies appearing on AndroGel's label and in the medical community at large. Dr. Perez made many presentations on behalf of Defendants, and delivered the AbbVie Defendants' marketing messages to hundreds of physicians. In essence, Dr. Perez was paid by the AbbVie Defendants to advocate for the systematic experimentation on non-hypogonadal patients with the off-label use of AndroGel.

e. ***Other Andropause-Related Off-Label Uses: Depression; Osteoporosis; and Sexual Dysfunction***

204. Sales representatives encouraged primary care physicians who were presented with middle-aged men complaining of various symptoms, such as depression or low sex drive, to

consider low, borderline, or decreased testosterone levels as a cause and to prescribe AndroGel to treat the depression, with or without prior blood tests showing abnormal testosterone levels. For example, a slide from an internal AndroGel business plan titled "Strategies to Enhance the Category" included the following statement of marketing intent: "Increase awareness of link between co-morbid conditions with enhanced messaging to physicians and patients." Of course, that "enhanced messaging" contemplated off-label marketing messages.

205. Indeed, one of the questions in the ADAM questionnaire geared toward depression patients and which is still available on the AbbVie Defendants' website reads: "Are you sad and/or grumpy?"

206. In a later internal sales planning document, the AbbVie Defendants noted that "We need to probe the physician to determine interest" in prescribing AndroGel for "fatigue and SSRI failures."

207. Other sales scripts for promoting AndroGel for depression were used widely. Suggested probes included: "How are you treating your male patients who present with fatigue and depression?" Similarly, a New Orleans district presentation concentrated on selling AndroGel to primary care physicians for men who fail on SSRIs.

208. Of course, many drugs are indicated to treat clinical depression, having been proven to be safe and effective in randomized placebo-controlled clinical studies, unlike AndroGel. In particular, several drugs within the SSRI class, are available in generic form, and are thus much cheaper (not to mention actually proven to be safe and effective) than branded AndroGel.

209. Approved AndroGel sales aids were devoted to patients with depression. These sales aids referenced studies noting an effect of testosterone on mood. Yet the AbbVie

Defendants admitted to their pharmaceutical representatives that the studies that supported improvement of depression through testosterone therapy only encompassed hypogonadal men. The AbbVie Defendants nevertheless used these inapposite studies to promote AndroGel for use in men in the normal testosterone range. The AbbVie Defendants marketed AndroGel for depression not just to primary care doctors, endocrinologists, and urologists, but also to psychiatrists. In fact, the AbbVie Defendants developed an additional sales aid on depression just for this purpose.

210. In a 2010 article published in the Journal of Psychopharmacology, Dr. Pope backtracked from his 2003 article, essentially conceding that there was no evidence that testosterone gel was effective in treating clinically depressed male patients.

211. Undaunted, the AbbVie Defendants have advanced these unsupported claims that AndroGel is safe and effective in treating depression, depressed men with normal testosterone levels who received AndroGel were deprived of medically effective and legitimate drugs that could have effectively treated their depression. Since AndroGel has remained a preferred branded drug on most formularies, TPPs were also required to reimburse for ineffective treatments and for additional doctor visits on account of a failure of therapy. Perhaps more concerning, however, is that depression can be linked to dangerous conditions such as cardiovascular disorders. Indeed, treating the symptom in lieu of investigating underlying causes risked patients' health.

212. The AbbVie Defendants also promoted AndroGel as an off-label treatment for osteoporosis in elderly men with potentially low or decreased testosterone levels. In a summer 2001 Peer Selling program in Shreveport, Louisiana, physician participant Dr. Glenn Cunningham, when asked "if any man with ANY sign of bone loss or bone mass decreases

should be treated with AndroGel," simply responded "YES!!!" The AbbVie Defendants dedicated sales aids to this use as well. The AbbVie Defendants' representatives and speakers pointed to data cited in AndroGel's label that suggested supplementing testosterone in truly hypogonadal men was linked with increased bone density. But any correlation was abject speculation. Even in studies that found a positive correlation between testosterone levels and bone strength, testosterone levels accounted for only about five percent of age- and weight-adjusted differences. Moreover, men with severely low testosterone levels showed improvement in the spine, but no change was observed in the hips, which are the sites of fractures that most commonly debilitate those with osteoporosis. Exposing elderly men to testosterone that increased risks of prostate cancer, cardiovascular adverse events, and other disorders in exchange for this illusory benefit to bone health was not only an off-label effort, but controversial at best for those without severe testosterone deficiency.

213. The AbbVie Defendants also promoted the off-label use of AndroGel as a substitute and/or add-on for Viagra in treatment of sexual or erectile dysfunction. A 2001 AndroGel detail used in the Southwest region declared its plan to "Ride coat tails of Viagra and SSRI market." For example, the call notes from a January 2001 sales call made by Solvay sales representative Ashley Thibeaux included this "everyone's doing it" response to a physician's assertion that he had no use for AndroGel: "You must be the only doc in town that doesn't prescribe Viagra." The AbbVie Defendants were undeterred by the limited or poor documentation demonstrating whether AndroGel was effective in treating erectile dysfunction. Viagra was considered a competitor drug in this sector, and the AbbVie Defendants coached sales representatives to ask doctors to substitute AndroGel for Viagra, particularly when patients continued to complain of dysfunction after treatment with Viagra. Again, this marketing scheme

placed patients at risk because patients did not receive effective treatment to determine the underlying cause of the sexual dysfunction, such as cardiovascular disease, which is much more highly associated with erectile dysfunction than hypogonadism. Indeed, lower hypogonadal levels of testosterone are in fact associated with decreased libido, and not with erectile dysfunction, in all but the rarest and most severe of cases. The AbbVie Defendants were and are happy to blur the lines between these distinct medical problems, and continue even today to promote AndroGel as a treatment for erectile dysfunction.

f. ***Off-Label Promotion of AndroGel to Women***

214. The AbbVie Defendants also promoted AndroGel for use in women despite specific warnings on the drug's label that women must not use it.[2] Solvay sales representatives actively pursued obstetricians and gynecologists routinely placed on representatives' target lists by senior managers. Estratest, an older Solvay drug, non-FDA-approved and containing both estrogen and testosterone, proved handy for marketing to these doctors. The AbbVie Defendants' representatives had already convinced numerous endocrinologists of the merits of Estratest and testosterone supplementation for increasing libido and well-being in women. The approach pitched to physicians was to treat symptoms; testing women's testosterone was not discussed or performed. It was simple to transition from Estratest to AndroGel with such physicians, now accustomed to supplementing testosterone without prior testing; they were already "sold" on the benefits for women (and easily coaxed to explore treating men as well).

215. To promote AndroGel's use in women, the company reworked an old non-branded brochure for women created to help drive demand for Estratest. The brochure was used

[2] The original 2000 label included the following contraindication: "AndroGel is not indicated for use in women, has not been evaluated in women, and must not be used in women." The same language appeared on the label until December 2007, when it was omitted, leaving in place a contraindication for pregnant women, and adding a contraindication for breastfeeding women. A new warning on the label stated: "Due to lack of controlled evaluations in women and potential virilizing effects, AndroGel is not indicated for use in women."

by the AbbVie Defendants' sales force nationwide. Though non-branded, the sales force well understood the brochure's purpose. For example, Tom Dovel, a district manager in the mid-Atlantic region expressly directed his sales representatives to use the brochure to detail physicians regarding the use of AndroGel in women. That brochure went through the AbbVie Defendants' usual internal review process when reworked in March of 2001 and the routing sheet shows clearly that the brochure was meant for promotion of AndroGel. The internal regulatory department approved the brochure for that use despite the warning on AndroGel's label that AndroGel "must not be used in women."

216. Furthermore, when Solvay Pharmaceuticals reprimanded sales representative Pia Nidiffer in 2003 for an AndroGel call on a doctor who treated only women, she responded that "everyone" promoted AndroGel to women, and others were not reprimanded. An internal Western region sales force newsletter from May 2002 reveals how casually the AbbVie Defendants' sales force engaged in such promotion; an article suggests better insurance coverage with, among other ICD-9 diagnosis codes, 256.3, which designates "Hypogonadism Female Hypogonadism Ovarian."

217. Women normally produce testosterone in levels significantly lower than in men, and maintaining those levels is associated with libido in women, just as in men. While testosterone supplements are sometimes recommended for women unable to produce testosterone (after full hysterectomy, for example), the AbbVie Defendants have never sought or obtained such an indication for AndroGel from the FDA, despite much post-launch talk that research would be forthcoming. Further, marketing AndroGel for women put these female patients at risk, because testosterone therapy in women generally requires smaller doses than the AndroGel packaging allowed to be metered out, and the drug's labeling did not reflect full associated risks

or directions for use. In particular, AndroGel was first packaged in small single-use packets. Sales representatives encouraged physicians to prescribe AndroGel to women and direct them to use a rough quarter of the pack at a time. The imprecise nature of the dosing was justified to physicians as a downside worth enduring because "anything's better than nothing" for women "in need of" testosterone supplementation.

218. Excessive testosterone in women produces serious adverse effects, such as acne, body hair growth, scalp hair loss, and a decrease in high-density lipoprotein (HDL) cholesterol levels, increasing the risk of heart disease. The balance between sufficient and excessive testosterone in women is a delicate one. An uncertain number of women likely suffered such adverse effects as a direct result of the AbbVie Defendants' marketing tactics.

219. Of course, the vast majority of (if not all) women who were prescribed AndroGel should not have been on any testosterone therapy whatsoever.

g. ***Off-Label Promotion of AndroGel to Target Patient Populations***

220. Recognizing that screening and testing of virtually any male population for "low testosterone" would lead to AndroGel scripts because of the over inclusiveness of the ADAM questionnaire and the unreliable nature of testosterone testing, the AbbVie Defendants have consistently aimed to expand the TRT market by identifying patient profiles with potentially higher incidences of hypogonadism and encouraging doctors to "screen, test and treat" these candidate patients. The AbbVie Defendants began, even before launch, by pursuing men over 45 years of age, HIV and AIDS patients, erectile dysfunction patients, and patients feeling fatigued or depressed as candidate patients that may be hypogonadal.

221. By 2002, the AbbVie Defendants had incorporated a plethora of chronic illnesses, such as diabetes, abdominal obesity (sometimes referred to as "metabolic syndrome" or "MS"),

chronic renal failure, rheumatoid arthritis, coronary atherosclerosis, and chronic liver disease, into its lists of target patient populations for which the AbbVie Defendants promoted AndroGel as an "add-on" to existing therapies. The AbbVie Defendants were exploring promotion for treatment of chronic pain by 2003. In short, the AbbVie Defendants promoted AndroGel as having as many potential uses as snake oil.

i. Off-Label Promotion for the Treatment of Diabetes

222. The AbbVie Defendants' internal marketing materials described a "Diabetes proof-of-concept." Of course, treatments based on "concept" without proof are not and should not be enough to garner FDA approval for treatment.

223. The AbbVie Defendants' approved AndroGel print ads that cited the HIM study and stated, for instance, that diabetic men were twice as likely to have low T. In the field, however, marketing became more direct. Representatives spoke about the difficulty of treating non-compliant, overweight diabetic men and suggested that AndroGel could help manage, or even improve, patients' diabetes. In addition, sales representatives were instructed to "Explore new opportunities with Hispanic and African-American populations." It was later specified that these ethnic groups were targeted for AndroGel's diabetes off-label messaging. Representatives claimed that AndroGel could increase such men's lean muscle, decrease their fat, get them moving off the couch, and, pointed in part to data on AndroGel's label that suggests insulin therapy for diabetics may be affected by testosterone levels, potentially eliminating the need for some diabetes medications. It was the AbbVie Defendants' upper management that directed AndroGel to be marketed for the treatment of diabetes, but training was often indirect and discreet.

224. A March 2006 Solvay Field Contact Report was more explicit: District Manager David Sharpe praised sales representative Laura Wheat for presenting the "diabetic message" to physicians. An internal marketing team plan from the same time period included a slide titled "Why diabetes?" and stated that "diabetes is a reachable channel" on account of symptom overlap. The same document further explained the strategy as "[g]row[ing] the market by getting new patients on TRT therapy through a targeted approach, through diabetes channels." As one example of how this marketing strategy was to be implemented, the AbbVie Defendants discussed direct-to-consumer advertising for AndroGel with, "banner advertising on targeted websites (diabetes websites)." District managers gathered at national meetings for instruction in the sophisticated science related to diabetes necessary for making the pitch, which was delivered by trainers or opinion leaders. District managers then returned to their respective districts to train their own representatives.

225. Diabetic patients are particularly at risk of cardiovascular adverse events, however. Without any data to support an indication for diabetes treatment, combined with recent outcome data showing elevated cardiovascular adverse events for AndroGel patients, the use of AndroGel in diabetes patients is inadvisable either as an add-on to existing diabetes treatment or as a replacement medicine.

226. In addition, some of the most effective diabetes treatments, metformin, for example, are generic and much cheaper than AndroGel.

ii. Off-Label Promotion for the Treatment of Obesity

227. Similarly, the AbbVie Defendants claimed that AndroGel could reduce fat and increase lean body mass in obese patients. In a January 2006 Solvay Field Contact Report,

District Manager Kevin Maher observed that one of his sales representatives, Twyla Jenkins, needed to present the "Fat Bob" piece when detailing physicians.

iii. Off-Label Promotion for the Treatment of Pain

228. The AbbVie Defendants' representatives suggested to physicians that men on long-term opioids experience a reduction in testosterone, and increasing testosterone could potentially supplement pain management.

229. The AbbVie Defendants' marketing managers described marketing efforts of AndroGel as a pain management medication as presenting an "opportunity for growth."

230. The AbbVie Defendants' sales representatives thus directed their sales efforts to pain management clinics, detailing the health care providers at such clinics on AndroGel's role in pain management for men.

iv. Off-Label Promotion for the Treatment of HIV/AIDS

231. The AbbVie Defendants have spent considerable resources marketing AndroGel to the HIV/AIDS patient population since AndroGel acquired a related orphan drug designation in 1996. But the AbbVie Defendants have never applied for an FDA indication for this use, apparently lacking the clinical support.

232. Immediately post-launch, the AbbVie Defendants began promoting AndroGel to treat AIDS wasting caused by a combination of food malabsorption, loss of appetite, and increased metabolism. Doctors sometimes prescribe steroids to HIV or AIDS patients with wasting to help replenish their lean muscle mass and body weight and improve physical endurance. The AbbVie Defendants used AndroGel's qualification as a steroid as the sole basis for marketing AndroGel as a treatment for wasting, lethargy and fatigue. In late 2001 or early

2002, the AbbVie Defendants actually created an AndroGel Specialty Sales Force that focused on marketing AndroGel to AIDS treatment centers.

233. The AbbVie Defendants' sales aids targeting this population consistently misstated clinical research and misled doctors about the prevalence of hypogonadism in those with HIV or AIDS in order to support routine screening and testing. The sales aids cited figures as high as fifty percent in the HIV+ population at large, even though the data only supported a thirty-eight percent prevalence, and then only in the days preceding anti-retroviral therapy, when AIDS was widespread, with nearly all hypogonadal test results from patients with full-blown AIDS. Many HIV clinics began routine testosterone testing as a result, often setting a somewhat high 350 ng/dL as the lowest normal level, while others employed the ADAM questionnaire as a screening tool first, despite the existence of clinical studies that show its failure to detect hypogonadal patients in this population. As a result of these deceptive practices, which included the addition of physician participants to the Peer Selling Enterprise with relevant expertise, AndroGel's use flourished.

h. ***The AbbVie Defendants' Widespread Use of Kickbacks to Induce Prescribing***

234. To drive up AndroGel utilization, the AbbVie Defendants engaged in particularly aggressive physician marketing efforts. The AbbVie Defendants bribed doctors to prescribe AndroGel. Whether the kickbacks took the form of bogus speaker and research fees, resort weekends, cash payments, or Harley Davidson goods, the motive was the same—to lock in patient referrals (i.e. prescriptions). The recipients of these attentions were the high actual or potential prescribers on representative's target lists.

235. In addition to tainting those prescriptions that arose out of these schemes, the AbbVie Defendants' kickback strategy raised the total cost assumed by health plans because

doctors, influenced by the AbbVie Defendants' remunerations, prescribed AndroGel that they would not have without the kickbacks.

236. Because the AbbVie Defendants' kickback schemes are intertwined with its off-label promotion of AndroGel, off-label prescriptions for AndroGel capture not only the cost of the AbbVie Defendants' off-label marketing, but also in many cases profits tainted by kickbacks.

i. Cash-for-Prescriptions to Induce Off-Label Prescribing of AndroGel

237. The AbbVie Defendants' executives, managers, PSAs and sales representatives developed several kickback schemes in order to provide "incentives" in the form of cash to high-prescribers and to induce other physicians to prescribe high volumes of AndroGel. Many of the cash schemes were variations on the same theme. For instance, one quasi-research theme was to pay doctors to fill out minimal paperwork on patients taking Solvay drugs, supposedly to further medical knowledge.

238. Another strategy was to pay potentially high-prescribing physicians bogus "consulting" or "speaking" fees that were in reality intended to be in exchange for writing increased amounts of AndroGel prescriptions.

239. The sheer number of these schemes, their similarity, sales representatives' high level of discretion with their budgets, and the sparseness of the obligations imposed on physicians in exchange for the cash, point to the conclusion that these "programs" were mere incentives/rewards for prescribing AndroGel. For example, one program involved "Get[ting] high volume [AndroGel] writers to training seminar" for which they would be reimbursed for their time. Another involved "Invit[ing] Top [AndroGel] writer to speak at employee health fair on Low T." Of course, to be considered for these programs (for which the AbbVie Defendants

paid handsomely), the physician needed to be a "Top [AndroGel] writer." In other words, the AbbVie Defendants sought to reward physicians for prescribing large amounts of AndroGel.

ii. Speaker Honoraria to Induce Off-Label Prescribing of AndroGel

240. The amount of speakers' honoraria, which varied and was negotiated on an individual basis by sales representatives, exceeded the fair market value and reasonable compensation ordinarily given to a speaker in a typical arms-length transaction, particularly as presentations were often short and the audiences small. Speakers were encouraged to speak at back-to-back events as often as several times a week, and no audience was considered too small.

241. Furthermore, the AbbVie Defendants frequently held speaker programs at upscale venues or luxury resorts and invited and paid for the speaker's family to attend as well. The AbbVie Defendants' management encouraged representatives to select creative venues for speaker programs such as holding them at sporting events and dinner cruises. The occasion for such resort weekends could be a marketing feedback panel, speaker training sessions, a regional or district Advisory Board meeting, or simply a conference inviting high prescribers in the drug class to hear lectures on a particular off-label topic. Even when the lectures to be given were accredited CMEs, the AbbVie Defendants violated company-adopted AMA standards by paying doctors to attend, which it accomplished by issuing $100 gift certificates and/or paying for travel and lodging.

242. For instance, Bert Stephens, Regional Sales Manager for the South Central Specialty Region, wrote a business plan for his seven representatives in 2001 in which he declared that he had "put aside $12,000 for each rep to invite 2-3 key High Potential HIV writers of Testosterone [AndroGel] to a weekend program at a desirable location."

243. Such weekends were also organized out of headquarters: the AbbVie Defendants' brand management team organized a conference for HIV specialists to promote AndroGel, held on May 17 to 19, 2002, entitled, "HIV Issues 2002: Managing Side Effect Complications." Fifty-nine attendee physicians and six physician faculty members spent a weekend at the Phoenician resort in Scottsdale, Arizona, involving six hours of meetings and plenty of time for golf and other "recreational activities," all paid for by the AbbVie Defendants. The off-label Saturday lectures promoted the use of testosterone, and, in particular, AndroGel, among HIV positive patients, and covered studies of such use in both eugonadal and hypogonadal men.

iii. Speaker Training Workshops

244. Speakers often attended Physician Speaker Facilitator Workshops ("PSFW") or Speaker Training Meetings for which the AbbVie Defendants allocated approximately $130,000 per program. An attachment to an October 8, 2001 e-mail from Shaji "Shawn" Durrani, Regional Marketing Manager - Cardiovascular for the South Central region, to the MTA-Field PC DM, Ed Maker and Michael Bullington contained the following description of these meetings:

> PSFW: A PSFW is a Speaker Training Meeting, identical to the ones which occurred in 2001. The cost of a typical program is $130,000, but cost may vary depending on your specifications. These meetings must fall in line with AMA guidelines and content is pre-determined by the home office. We recommend at least one of these per region in 2002. More than a few per region could be suspect, as one only needs so many speakers.

245. From January to June 2001, sales representatives in the Southwest region signed up four doctors to participate in the AndroGel speaker training program that Durrani described. Later in the year, sales regions apparently stopped worrying about suspicion attached to selecting numerous doctors; by then, the AbbVie Defendants had held "Physician Speaker Facilitator

Workshops" to train 291 regional urologists and endocrinologists to speak on the "importance of TRT and the critical role of Andropause."

iv. AndroGel Marketing Feedback Panels

246. Marketing feedback panels, or focus panels, were among the AbbVie Defendants' earliest and most abusive kickback schemes, used in promoting AndroGel. Sales representatives would invite doctors from across the country to fly to a luxury hotel or resort and listen to speakers promote AndroGel. The AbbVie Defendants not only paid for each doctor's airfare and lodging, but paid each doctor an attendance fee to attend the speaker's program. To attempt to legitimize this scheme, the AbbVie Defendants' representatives called the doctors "consultants," and asked them to comment afterwards on the effectiveness of their sales pitches.

v. District or Regional Advisory Boards

247. The AbbVie Defendants also used district or regional advisory boards as a way to funnel kickbacks to physicians. The AbbVie Defendants gathered local physicians for the supposed purpose of providing feedback on how to market AndroGel. These district or regional advisory boards were open venues where off-label indications of AndroGel would be discussed. In exchange for participating in these events, the physicians would each receive a fee or honoraria.

248. Durrani's October 8, 2001 email gave the following description of regional advisory programs for use in promoting AndroGel:

> Regional Advisory Panel: Physicians attending a Regional Advisory Panel are paid consultants. Too many of these programs could be suspect, as one only needs so many physician advisors. These programs will likely be conducted with the help of your Medical Liaisons. We recommend 0 to 4 per region, but you may do as many as you please.

249. In other words, Durrani was cautioning that paying too many physicians as "advisory board consultants" would arouse the suspicion that these were, in fact, kickbacks for prescriptions.

vi. Dinner Meetings with Speakers and Other Speaker Events to Induce AndroGel Off-Label Prescribing

250. The AbbVie Defendants hosted multiple types of dinner meetings. No matter the type, these meetings often ran afoul of the Anti-Kickback Statute as well as OIG, AMA, PhRMA, and ACCME guidelines because they involved (1) sham consultants' fees for attendees, (2) met at entertainment venues, such as skyboxes at football games, or (3) involved spouses or children. See Anti-Kickback Statute, 42 U.S.C. § 1320a-7b; Department of Health and Human Services, Office of Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers, 69 Fed. Reg. 23,731 (May 5, 2003); PhRMA Code; AMA Opinion 8.061; ACCME standards. Some combined these attributes, any of which would alone be enough to violate the Anti-Kickback Statute as well as OIG, AMA, PhRMA, and ACCME guidelines. All of them routinely focused on off-label material to the extent that they had any substance or purpose beyond "relationship-building."

251. Justifying costs to managers was a potential concern, but abiding by the Anti-Kickback Statute as well as OIG, AMA, PhRMA, and ACCME guidelines was surely not. The AbbVie Defendants held programs at gourmet wine galleys and skeet shooting grounds – virtually any kind of entertainment venue was eligible. The AbbVie Defendants' venues and excessive compensation reveal that the focus of these speaker programs was on wining and dining doctors rather than on exchanging scientific and medical information, which even when done was to support the off-label uses of AndroGel.

252. Pampering doctors with expensive dinners induced attendees to prescribe the AbbVie Defendants' drugs, including AndroGel.

253. One example was a so-called "case exchange" for AndroGel. The AbbVie Defendants used case exchange programs for promoting AndroGel off-label. Durrani's October 8, 2001 email described the AndroGel case exchange program as follows:

> Case Exchange: Case exchange programs are under development at this time, but will involve physician interaction and presentation of case studies. These programs will be similar to those conducted with ACEON in 2001. Our cost estimate for one of these programs is $4,500, but could vary. You may conduct as many or as few of these programs as you please.

254. These were effective programs. According to an Oklahoma City district business plan, "monitored attendees from [2001's] AndroGel [sic] case exchange are writing" more AndroGel prescriptions.

255. Roundtables were popular among sales representatives for promoting AndroGel. In 2001, sales representatives chose respected urologists and endocrinologists who believed in AndroGel, and asked them after viewing the representative's target list, to choose four or five primary care physicians who refer to them. $500 was the typical speaker's fee.

256. Roundtables could be formal or less formal events, and even became full-fledged resort weekends in some cases.

vii. Regional "CAST" Programs to Drive Off-Label AndroGel Message

257. In promoting AndroGel, the AbbVie Defendants' brand management developed a series of $15,000 regional "CAST" programs to be held in 2002, designed to train doctors to drive press coverage. Program materials include a presentation on promoting AndroGel for sexual dysfunction and other uses, drafted by public relations firm Edelman Worldwide, which

had also partnered with St. Louis University and Solvay to promote the ADAM questionnaire. The firm noted that topical stories, such as the FDA's recent approval of sexual dysfunction drugs, may allow doctors "an opportunity to reach out to reporters and ensure they understand testosterone's role in sexual dysfunction and on libido." Drs. Glenn Cunningham and David Kaufman served as "moderating faculty."

258. As a result, paid physicians were trained to and began vigorously defending AndroGel use when interviewed by media.

259. For example, addressing the dearth of adequate evidence supporting TRT efficacy, Dr. Larry Lipshultz, a frequent Solvay speaker, asserted the following: "There is no reason to withhold treatment from patients with symptoms and lab reports of low testosterone levels because someone has not done a placebo-controlled study." Of course, Dr. Lipshultz was on the speakers' circuit for the AbbVie Defendants, and was actually telling doctors to ignore lab values and to focus exclusively on symptoms associated with the normal aging process.

260. Solvay even recruited speakers at such "CAST" programs to begin disseminating AndroGel off-label messages to prescribing physicians. By July 31, 2002, Solvay's district manager for the Kansas City District was reporting that three doctors had attended a CAST meeting in Topeka and that Solvay was now working on cultivating these doctors as speakers, or physician participants in the Peer Selling Enterprise.

viii. Preceptorships to Induce AndroGel Off-Label Prescribing

261. Another of the AbbVie Defendants' kickback schemes involved preceptorships. A "preceptorship" describes a fictitious business arrangement where a doctor grants a pharmaceutical representative the privilege of shadowing him/her for part of a day (usually four to eight hours), and in exchange for this "tutelage," receives an honorarium. During this time, the

representative gets the added benefit of promoting the AbbVie Defendants' products, including AndroGel, to a captive (and usually already receptive) audience. The AbbVie Defendants used preceptorships to market AndroGel's off-label uses to doctors. Indeed, the AbbVie Defendants mandated that its representatives participate in at least four preceptorships per month. In exchange for allowing the representative to "shadow" them, the AbbVie Defendants paid the doctors anywhere from $150 to $1,000.

262. For example, the Kentucky district from January through June 2001 set aside $4,500 for nine (9) AndroGel preceptorships.

263. Such preceptorships were thinly-disguised kickback payments to high prescribing physicians.

ix. Honoraria and Grants for Bogus Clinical Trials, Studies and Focus Panels to Induce Off-Label Prescribing of AndroGel

264. Solvay and Unimed, a Solvay company, instituted an AndroGel screening program called ALERT sometime before 1999. It continued until sometime in or before 2002. It originally involved a one-day screening event plus patient follow-up. The program was later extended beyond the one-day screening events, and representatives began to pay doctors in the form of a $500 "speaker's honoraria;" doctors continued to log new patients on the AbbVie Defendants screening forms, and representatives periodically collected the logs. A report on ALERT for the first half of 2001 shows that the Shreveport district paid $16,500 in ALERT "honoraria" and owed a further $22,000, with 397 patients screened – nearly three times the original goal of 135. In one example, a physician apparently received $500 in ALERT funds on May 11, 2001 for participating in a screening later that month. A completed ALERT patient log from one of Tonya Stringer's target physicians reveals that even patients who screened "negatively" received a testosterone test, and some of those patients were prescribed AndroGel.

Participating physicians, both specialists and primary care doctors, signed written agreements promising to advertise the screening event and to identify those among their patients who might suffer from hypogonadism.

265. Under the ALERT contract, physicians were to be paid $500 upon "completion" of the program. For example, from January to June of 2001, Sales Representative D. Pallone placed ALERT kits with four different doctors, who screened an average of sixteen patients per doctor for a total of sixty-three patients. The four doctors had been paid a total of $1500 in "honoraria," with more funds requested as of the date of the report. During the same time period, sales representative Tonya Stringer provided ALERT kits to twelve doctors, who screened an average of ten patients, for a total of 125 patients. A total of $3,500 in honoraria was paid to these doctors.

266. In addition, participating doctors and nurses were given pre-paid calling cards containing up to 20 minutes of free calls per patient, for up to 40 patients. Ten minutes could be earned per patient by reporting patients' symptoms, ADAM questionnaire results and giving a blood test. Ten additional minutes could be earned by reporting blood test results and any drug prescribed. Finally, the AbbVie Defendants also provided funds for doctors to advertise their screening events, and to cover the expense of adding the ADAM questionnaire to patient history forms.

267. Physicians were told that the AbbVie Defendants would collate the content of the logs for a study, but the study never appeared. ALERT was in essence a plan to pay doctors for enrolling patients on AndroGel, as evidenced by the AbbVie Defendants' decision to pay doctors additional fees when they continued screening after the screening day was over, and physicians' expectations that further checks would ensue.

x. Non-Cash Kickback Schemes to Induce Off-Label Prescribing of AndroGel

268. In addition to the cash-for-prescriptions schemes, the AbbVie Defendants had other non-cash kickback schemes.

269. One non-cash scheme was the "Nurse Betty" program. This was a program to promote AndroGel that the AbbVie Defendants first rolled out in urban areas in the Southwest region in 2002, with plans to expand into larger areas incrementally, as announced in a March 2002 mid-POA AndroGel presentation to the sales force. The AbbVie Defendants hired nurses to work within doctor's offices for the sole purpose of identifying and screening patients for AndroGel use. Doctors and their staff were freed from such screening, potentially allowing them to see more patients. Brand management discussed potential expansion of this program at POA meetings.

270. "Stock Bottles" were another non-cash scheme. The AbbVie Defendants focused distribution of drug samples to its top prescribers. Samples were in short supply, and in order to influence key doctors, the AbbVie Defendants reminded representatives to reserve "stock bottles" for the top 25 or "gold" physicians. Regional Business Director Christa Townsend told John King on February 14, 2002, that higher market share territories would receive "an ADDITIONAL supply of the stock pkgs."

271. The AbbVie Defendants use "Lunch-N-Learns" and other non-cash incentives tied to off-label sales details. In Lunch-N-Learns, representatives would bring in food from a popular restaurant for a doctor and his or her staff. During the lunch, representatives would play media or otherwise disseminate information on the off-label uses of AndroGel. The AbbVie Defendants viewed these Lunch-N-Learns (or "L&Ls") as a way to "Tailor education content … to augment selling efforts" and noted that they "Provide value from outside venue."

272. Lunch N' Learns were and remain a staple of the AbbVie Defendants' drug promotion. For example, the Kentucky district budgeted $25,200 for Lunch N' Learns for the first half of 2001. Lunch N' Learns employed for AndroGel not only involved the provision of an item of value – a meal – in exchange for listening to a detail and ultimately writing scripts, but consistently concerned off-label topics. Sales representatives sometimes set up Lunch-N-Learn speaker programs at local restaurants rather than offices, particularly when more than one doctor was invited.

273. "Dine N' Dashes" were another form of non-cash scheme. Dine N' Dashes followed the Lunch N' Learn model except in one important respect: the doctors took the AbbVie Defendants' free meals home to their families, which is strictly forbidden by the PhRMA code. The AbbVie Defendants' representatives chose a popular restaurant and invited doctors to stop by to pick up dinner. Each doctor then ordered a take-out meal for the doctor's entire family. While the doctor waited for the order, the sales representative gave a sales pitch on the off-label uses of AndroGel. The AbbVie Defendants frequently chose expensive restaurants for Dine-N-Dashes. The AbbVie Defendants spent anywhere from $150 to $300 per doctor in feeding the doctors and their families. These meals were clearly for the doctor's personal benefit and conferred no benefit on patients.

274. As an example of a Dine N' Dash, on February 1, 2001, Solvay sales representatives Stuart McCown and John Burleigh organized an event involving detailing approximately fifty prescribers at Outback Steakhouse in Baton Rouge, Louisiana regarding off-label uses of AndroGel. Dine-N-Dashes were popular forms of remuneration in Houston, too, because "they [] worked in a big way" there.

275. From February to June 2000, sales representatives in the Cape Fear, North Carolina district set aside $13,350 for twenty-six Dine-N-Dash programs. For example, on February 23, 2000, Solvay sales representative Bill Riddick from the Cape Fear territory planned to spend $1000 for fourteen doctors on a Dine-N-Dash at New Towne Bistro in Winston-Salem, North Carolina. Solvay sales representative Shannon Zeko from Cape Fear territory planned to spend $500 each on five Dine 'N Dash events, for a total of $2500, at various restaurants in Wilmington, Lumberton, Clinton, Whiteville, and Southport, North Carolina.

276. By 2002, pharmaceutical representatives from other companies understood Dine-N-Dashes to be what they truly were: kickback schemes. Solvay co-promoted AndroGel with TAP Pharmaceuticals at that time. On March 28, 2002, Solvay representative John King emailed his TAP counterpart, Alvin Reine, about initiating a new series of roundtables with urologists as moderators and primary care physicians as attendees. Reine replied with a willingness to coordinate TAP's participation, but added, "I do need some clarification as I have heard that some Solvay reps are setting-up [sic] programs in which the doctors are able to take a meal home and I will state that TAP will not participate in any such programs as they are closely related to the dreaded "Dine and Dashes."" Despite this one representatives' uneasiness about the program, TAP's sales force participated in all aspects of AndroGel co-promotion.

277. The AbbVie Defendants also used "Book-N-Dashes" as non-cash inducements. For a Book-N-Dash, Solvay representatives would invite doctors to stop by a bookstore. Each doctor then received a gift certificate to the store. While the doctor waited for the certificate, the sales representative gave a sales pitch on AndroGel. For example, from February to June 2000, sales representatives in the Cape Fear, North Carolina district set aside $2,000 for four Book-N-Dash events. Solvay sales representative Shannon Zeko hosted a Book-N-Dash at a Barnes &

Noble in Wilmington, North Carolina on February 19, 2000, spending an estimated $500. Likewise, sales representative Phyllis Gordon hosted an event at Sloan's Book Shop in Waynesville, North Carolina on March 23, 2000 for an estimated $500. Solvay sales representative Austin Vaughn conducted two Book-N-Dash events: one on March 15, 2000 at Barnes & Noble in Greenville, North Carolina, and one on April 19, 2000 at Hasting's Books & Music in Rocky Mount, North Carolina, spending an estimated $500 for each event. Books-A-Million was a popular venue in the Birmingham district for similar events.

278. The AbbVie Defendants also conduct "Flowers-in-a-Flash" to induce sales, an identical scheme to those above but with a florist's shop. One of the AbbVie Defendants' sales representatives would offer physicians free flowers at a local flower shop, particularly around special holidays, such as Valentine's Day. When the physicians came to pick up the flowers, the sales representative would take the time while the physician was waiting to promote off-label uses of AndroGel. These were popular events with physicians.

xi. Gifts to Induce Off-Label Prescribing of AndroGel

279. In August 2000, David Neuberger (Senior Internal Auditor at Solvay America) sent a memorandum to Bob Solheim (Vice President of Finance and Administration), Ann Willmoth (Vice President of Sales), Barb Casey (Director of Training and Development) and Chip Dale (Controller and Chief Accounting Officer) at Solvay Pharmaceuticals and copied Morris Attaway (internal auditor at Solvay America), and Phil Uhrhan (Vice President of Finance for Solvay America). Neuberger challenged many of the expenses claimed by Solvay Pharmaceuticals' contract sales representatives as inappropriate given the AMA guidelines' prohibition on physicians' acceptance of gifts of substantial value. The July 2000 memorandum concluded, "We question if these 'serve a genuine educational function' and are appropriate."

280. In complete disregard of the company compliance policies and the AMA guidelines, Solvay induced doctors to prescribe Solvay's drugs by seducing them with gift certificates to their favorite stores of substantial value. Some examples of gift certificates offered in Texas found in Neuberger's audit are typical of the nationwide practice. For example, in February and March 2000, Solvay representative Shana Lodar gave Houston doctors gift certificates to restaurants in the amounts of $200, $300 and $625. Similarly, an Austin representative gave a doctor a $203 gift certificate to a sporting goods store, Academy Sports & Outdoors. Particularly egregious were the gift certificates for limousine rides in Houston and Dallas worth up to $700. The AbbVie Defendants' practice of giving doctors gift certificates was plainly an attempt to induce doctors to prescribe AndroGel off-label.

281. The AbbVie Defendants blatantly bestowed upon doctors personal items, often geared towards the doctor's specific interests or hobbies. The AbbVie Defendants frequently gave doctors tickets to entertainment events. Indeed, representatives would send doctors a photocopy of event tickets with a note stating that the tickets were available if the doctor would listen to the representative's pitch for two minutes. Thus, one Beaumont representative gave a doctor $930 worth of Houston Astros tickets, while a Houston representative gave a doctor $300 worth of Astros tickets.

282. Similarly, the AbbVie Defendants' representatives gave doctors a variety of expensive personal gifts ranging from spa packages, Harley Davidson jackets, bowling balls, big game hunting trips, hunting supplies, artwork, golf equipment, and coupons (to Starbucks and Blockbuster, among other stores). For example, on March 15, 2000, a sales representative, William Coad, gave a $200 Eddie Bauer gift certificate to a doctor. Another representative, Ashley Thibeaux, in the Southwest region, spent $922 on a golf outing on March 15, 2000.

These gifts are just some of the remuneration Solvay paid in exchange for prescriptions. In another example, one Alabama-based district manager in an internal presentation announced plans for an AndroGel "Skeet shooting program with Specialty rep" and a "Tap Shootout annual skeet shooting program funded by Tap."

283. The AbbVie Defendants' off-label marketing efforts survive to this day. Defendant AbbVie spent $80 million promoting AndroGel in 2012, not including the many millions spent on crucial DTC advertising intended to inflate disease state prevalence and attract off-label usage.

B. The AndroGel Publication Enterprise

284. In order to carry out their AndroGel Publication Enterprise, the AbbVie Defendants and their associates exercised close control to ensure that their off-label marketing messages were prominently included in seemingly unbiased clinical studies which were in fact the opposite.

285. One particular example is an article published in the American Journal of Medicine promoting AndroGel for HIV/AIDS patients, discussed *infra*. Tying the Publication Enterprise back to the Peer Selling Enterprise, Defendants ordered reprints of these articles by the thousands, and, along with its Peer Selling Enterprise participants as well as its own sales force, distributed them to physicians, P&T Committees, and PBMs purportedly as credible and independent results of unbiased scientific studies.

286. For example, the AbbVie Defendants instructed their sales force that a "best practice" was to provide physicians with "Approved Clinical Reprints" supporting off-label uses of AndroGel, including the "POPE paper [that] supports the patient profile that we provide to physicians to address the depressed patients on SSRIs." Another reprint Defendants' frequently

distributed was the "Wang Study," which could have referred to any number of favorable studies published by Dr. Christina Wang. Of the three (3) publications referenced on the AbbVie Defendants' efficacy webpage for AndroGel, Dr. Wang is listed as the primary author on two (2) of the publications and the second-listed author on the third one. (*See* www.androgelpro.com/1-percent/efficacy.aspx). The two (2) "Wang Studies" (on which Dr. Wang is listed as the primary author) literally list the "kitchen sink" of the AbbVie Defendants' favored off-label promotions in their titles. Defendants also trained physician participant speakers on how to present such study results at speaking events, including supplying the physician participant speakers with slide decks containing desired marketing messages to be used in their presentations. In receiving an award from the American Society for Andrology ("ASA"), the ASA stated that Dr. Wang was "a role model and mentor for a generation of students, residents and fellows." Notably, Dr. Wang is a physician participant in the Peer Selling Enterprise, and has on numerous occasions disclosed consulting and advising relationships with the AbbVie Defendants, along with a number of other pharmaceutical companies.

287. In 2005, the AbbVie Defendants began relying on a yet-to-be-published study "authored" by Thomas Mulligan, a frequent beneficiary of Solvay funds and Peer Selling and Publication Enterprise associate. Mulligan's study, "Prevalence of Hypogonadism in Males at Least 45 Years: the HIM Study" ("HIM study"), which was eventually published in 2006, concluded that a whopping 38.7 percent, roughly 13.8 million, of American men over forty-five years of age seeing primary care doctors for any reason are hypogonadal, dwarfing the MMAS's estimated population. *See* HIM Study, *available at* http://www.ncbi.nlm.nih.gov /pmc/articles/PMC1569444/ (last visited June 20, 2014).

288. The HIM study was funded by Solvay and co-authored by Dr. Cecilia McWhirter, a Solvay employee, and by several employees of vendor participant Covance Peripproval. Under the "Commercialization" section of their website, Covance exhorts its pharmaceutical clients to "Create your Own Success" by "[p]rov[ing] your product value to a diverse group of stakeholders, most importantly … payers." The HIM Study did just that; by polluting the medical literature with a study that has been re-cited thousands of times by TRT Defendants and their vendor and physician participants, the AbbVie Defendants created a market out of thin air where AndroGel could become a blockbuster drug.

289. Naturally, the AbbVie Defendants planned to capitalize on the HIM Study results, with one business plan exhorting the sales force to "Utilize HIM Study Publication in Reprint carrier format." The same plan suggested spending $75,000 on HIM Study reprints to be distributed to physicians to "increase product visibility and disease state awareness through wide-spread dissemination of clinical data."

290. The promotional (as opposed to scientific) nature of the HIM Study, including the true extent of the AbbVie Defendants' involvement in developing the study, was never adequately disclosed to physicians.

291. For additional support in challenging definitions of hypogonadism, representatives were instructed verbally and in writing when "detailing" doctors to rely on the American Academy of Clinical Endocrinologists' ("AACE") 2002 consensus guidelines. These guidelines discussed the potential treatment of men suffering from hypogonadism caused by "aging" with "low-normal" testosterone levels as high as 400 ng/dL, which was 100 ng/dL within the normal range as understood in the studies cited on AndroGel's label.

292. The guidelines were circulated to the sales force with a cover letter warning representatives to use them promotionally, but without mentioning "Andropause." While the cover letter made the point that the AbbVie Defendants had not funded AACE, at least two of four committee members for AACE (Drs. Ronald Swerdloff and Richard F. Spark) at the time had long received Defendants' funding, and were physician participants in the Peer Selling Enterprise.

293. In a 2013 study published in the Journal of Adolescent Health, on which Dr. Swerdloff was an author, he disclosed serving as a consultant for Defendant AbbVie. Notably, AbbVie disclosed that it designed the study and undertook the collection, analysis, and interpretation of the data, and drafted the manuscript and made the decision to publish the manuscript. In light of AbbVie's disclosures, Dr. Swerdloff's role (as well as the role of the other "authors") remains unclear. Rogol, et al., *A Multicenter, Open-Label, Observational Study of Testosterone Gel (1%) in the Treatment of Adolescent Boys with Klinefelter Syndrome or Anorchia*, 54 J. Adolescent Health 1:20-25 (Jan. 2014). Furthermore, Dr. Swerdloff also was an author on at least one uncontrolled AndroGel study funded by Defendants supporting a host of off-label uses for AndroGel: Wang et al., *Long-Term Testosterone Gel (AndroGel) Treatment Maintains Beneficial Effects on Sexual Function and Mood, Lean and Fat Mass, and Bone Mineral Density in Hypogonadal Men*, 89 J. of Clin. Endocrinol. Metab. 2085-2098 (2005).

294. As a crucial part of the Publication Enterprise, the AbbVie Defendants paid influential thought and opinion leader physicians to research and/or write about the specific off-label uses that provided the most promise in terms of profits. Many of these payments took the form of large "unrestricted educational grants" that were anything but unrestricted.

295. Some grants supported research, but the research activities (including study designs and protocols) were closely controlled by the AbbVie Defendants. Drs. Christina Wang, Harrison Pope, Molly Shores, John Morley, and Adrian Dobs, among others, all received research grants to study AndroGel.

296. One example of a study widely used by the AbbVie Defendants to support off-label sales of AndroGel was the previously discussed "HIM study," which was "authored" by Thomas Mulligan, a frequent beneficiary of the AbbVie Defendants' funds for services listed as "consulting," and co-authored by a Solvay employee. Even though Thomas Mulligan is listed as the lead author (and thus the cited author), upon information and belief, the "HIM Study" was authored primarily if not exclusively by the AbbVie Defendants' employees or a medical communications company hired by the AbbVie Defendants, who had predetermined the study's results and had the intention of using it promotionally. Indeed, the AbbVie Defendants were promoting the study's results before it was even published. In other words, as part of the Publication Enterprise, Mulligan lent his name for a fee to give the study additional credibility.

297. Other authors of medical journal publications received payments from the AbbVie Defendants, in addition to fees for speaking, consulting, and serving on advisory boards, with the expectation that they would receive funding for clinical studies and articles developed from those studies designed to support the off-label marketing of AndroGel.

298. As further examples, the 2003 edition of DRUGDEX lists a study published in the Journal of Urology on the use of AndroGel to treat sexual dysfunction in men authored by S. Arver, Adrian S. Dobs and A. Wayne Meikle. *See* Arver S, Dobs AS, Meikle AW, et al., *Improvement of sexual function in testosterone deficient men treated for 1 year with a permeation enhanced testosterone transdermal system*, 155 J Urol 1604-1608 (1996). The

study's conclusion directly benefited one of the AbbVie Defendants' most disseminated off-label messages, increased sexual function. As stated in the article's abstract, the conclusion was that "sexual function improved significantly in men with hypogonadism treated with the testosterone transdermal system." Dr. Dobs has long been a paid speaker and consultant for the AbbVie Defendants.

299. The AbbVie Defendants did not disclose to DRUGDEX (nor physicians or health plans) the nature of its financial relationships with and influence over entities such as the Endocrine Society or the University of Wisconsin. The AbbVie Defendants did not reveal the role of marketing consultants such as EDU-Medical or Dowden Health Media in its research activities. Nor did the AbbVie Defendants reveal even the status of its NDAs pending before the FDA. It was as a direct result of the AbbVie Defendants' deception and manipulation that AndroGel was able to gain the inclusion of a number of off-label uses in DRUGDEX in the hopes of legitimizing such uses.

300. The AbbVie Defendants exercised control over both study designs and resulting medical literature, which was either drafted by their employees or by a medical communications company and signed by the study authors in a practice known as "ghostwriting," or which was reviewed and heavily edited by the AbbVie Defendants' employees to ensure that the literature contained the appropriate off-label marketing messages for AndroGel. "Ghostwriting" is a particularly damaging form of pharmaceutical marketing. The drug company and/or its retained medical literature vendors author what is represented as an independent scientific paper, and pays an OTL to place their name on the paper as its author to give the appearance of objectivity and credibility, suggesting that the OTL performed the research and authored the paper. Effort is made by the pharmaceutical company to ensure that the specific marketing messages for the drug

are placed in these ghostwritten articles as frequently as possible. The pollution of the medical literature for AndroGel was particularly damaging to Plaintiff and the Class Members, who, in reviewing drugs and making formulary decisions, rely extensively on medical literature purportedly written by respected thought leaders, such as prominent endocrinologists and urologists.

301. In an August 2013 article published in JAMA's internal medicine journal, Stephen R. Braun (who is not even a physician according to his website, http://braunmedicalmedia.com/background.html (last visited June 20, 2014)), discussed his experience as an AndroGel "ghostwriter" for the AbbVie Defendants as part of the Publication Enterprise. *See* Braun, *Promoting 'Low T': A Medical Writer's Perspective*, 173 JAMA Intern. Med. 1458-1460 (2013). In the article, Braun describes ghostwriting articles from 2009-2012 for physicians, ghostwriting patient education materials, and ghostwriting "consensus" physician panel statements, all of which were funded by the AbbVie Defendants.

302. For example, relating to the "consensus" panel statements, Mr. Braun writes that, "[i]n 2012, I was hired by a professional physicians' organization to attend a meeting of experts in the field of hypogonadism and to write a summary of the meeting's conclusions – a "consensus" statement – to be published as a guide to clinical practice. In this case consensus was not difficult to achieve because … [t]he meeting was funded by Abbott, and every panel member had served as either a consultant or researcher for Abbott or other companies with TRT products on the market or in the pipeline (i.e., Auxilium, Endo Pharmaceuticals, and Defendants)." Of course, the resulting monograph was published and used by Abbott-paid lecturers during Abbott-funded CME courses, promoting increased utilization of TRT drugs

generally and of AndroGel for off-label uses (the physician-lecturers' slide decks were also ghostwritten by Mr. Braun).

303. Of course, in the interest of receiving continued ghostwriting business, Mr. Braun's spin was decidedly more industry-friendly than more neutral perspectives, such as that of Dr. Adriane Fugh-Berman of Georgetown University, who has researched the practice intensively and described it as outrageous and intensely damaging to the field of medicine.

304. Having distorted the medical literature with its off-label marketing messages for AndroGel, the AbbVie Defendants then ordered reprints of the various articles by the thousands as part of its Peer Selling Enterprise. Sales representatives, armed with these reprints, distributed them to physicians on sales calls, highlighting the embedded marketing messages as the medical opinions of the physician thought leaders attributed as authors.

305. The AbbVie Defendants also paid for and developed symposia through "educational grants," and the materials presented were largely created and controlled by the AbbVie Defendants and their associates. The materials were often later published in medical journals.

306. The AbbVie Defendants and/or their associates also sought out supposedly independent associations of specialists to issue "clinical practice guidelines" or "consensus guidelines" in favor of controversial positions that impacted its AndroGel sales. The simultaneous lobbying and financial support of the Endocrine Society and its officers by the AbbVie Defendants and their associates, discussed above, is an example.

307. The resulting literature provided off-label and deceptive selling points for sales representatives' detailing and for speaker program lectures, but more fundamentally, at the highest levels, it influenced the way TPP clinical decision-making was framed. These decisions

took place among P&T Committees and PBMs, including among Plaintiff and the Class Members, in their efforts to determine an appropriate formulary placement for AndroGel. Plaintiff and the Class Members were deprived of the opportunity to come to an appropriate decision regarding AndroGel's reimbursement status since the materials shaping the debate had been altered by Defendants.

308. Once the favorable clinical studies had been published, the AbbVie Defendants and/or their associates stamped an imprimatur on such medical literature by submitting them to prestigious medical journals and medical compendia such as DRUGDEX. Because DRUGDEX imposes few or no editorial requirements for inclusion, the mere listing of a use or study can convey an air of legitimacy to the poorest scientific effort. As CMS has declared, a mere listing is therefore not "supportive" for purposes of rendering a use "medically accepted."

309. The AbbVie Defendants and their associates likewise used the Publication Enterprise to convince doctors that men with hypogonadism or decreased testosterone levels frequently suffered from depression-like symptoms; thus, if AndroGel helped the patient's depression, low testosterone would be shown to be the underlying cause.

310. The AbbVie Defendants developed, sponsored, and paid for a study on testosterone and depression, the Pope Trial, reprints of which sales representatives distributed widely. *See* Pope, Jr., *et al. Testosterone Gel Supplementation for Men with Refractory Depression: A Randomized, Placebo-Controlled Trial*, 160 Am. J. Psychiatry 105-111 (2003). The only evidence of the AbbVie Defendants' involvement from the face of the article is the statement tucked at the very end that the study was "[s]upported in part by a grant from Unimed Pharmaceuticals Corporation." Sales representatives received comprehensive training on depression, mood, and physiological effects of low testosterone, even as they were told not to

discuss the Pope trial. In fact, handwritten notes from a June 26, 2001 Southwest Regional POA II meeting show explicit instruction on making the pitch:

- How are you treating depressed/moody men?
- How is this working?
- Do you ever have SSRI patients that have sexual dysfunction?
- How would it be if you could eliminate that problem?

311. The AbbVie Defendants also made numerous grants, totaling nearly $100,000, to a Seattle-based psychiatrist named Dr. Molly Shores, who served as the lead author on several articles asserting that AndroGel was effective in treating clinically depressed patients. In addition to research funding, Dr. Shores also served as a consultant to Defendant Solvay, and received an unknown amount of compensation. In one of these studies, Dr. Shores and her co-authors found that TRT could be effective in treatment of depressed elderly male patients. Shores et al., *A randomized, double-blind, placebo-controlled study of testosterone treatment in hypogonadal older men with subthreshold depression (dysthymia or minor depression)*, 70 J. Clin. Psychiatry 1009-1016 (July 2009). However, the AbbVie Defendants have yet to disclose the results of this study, as reflected on www.clinicaltrials.gov, despite the fact that the study has been completed since November 2006. Despite being a trained psychiatrist, Dr. Shores has served as lead author on several cardiovascular observational studies allegedly supporting TRT cardiovascular safety.

312. What the AbbVie Defendants' Publication Enterprise concealed is that AndroGel and TRT therapy carries serious cardiovascular health risks. As stated in Time Magazine's August 2014 article, "trusting testosterone to relieve men of aging amounts to a massive science experiment with unknown risks." However, as is becoming increasingly clear, whatever the unknown risks, the known risks include serious cardiovascular adverse events associated with vein and arterial blood clotting, including stroke, heart attack, and pulmonary embolism.

C. The AndroGel DTC Enterprise

313. The AbbVie Defendants and their associates engaged in AndroGel DTC marketing, promotional, and comprehensive educational campaigns through a variety of educational, advertising, and informational multimedia platforms.

314. Targeted DTC advertising of AndroGel was designed to drive patients to ask their physicians for prescriptions for AndroGel. Unbranded DTC disease state marketing was thus undertaken by the AbbVie Defendants and their associates, and was geared specifically toward expanding the definition of hypogonadism and/or branding Andropause as a recognized disease state in need of treatment. One of the AbbVie Defendants' AndroGel annual business plans described the AndroGel "Vision" to "Lead and Expand the TRT market" and to "Enhance the Category."

315. Beginning before launch, but peaking in late 2001 as the TAP co-promotion began in earnest, AndroGel brand managers, along with Solvay's vice presidents of sales and marketing, formed a strategy to focus, not on winning market share from rivals, but on "making a bigger pie" by essentially expanding the definition of hypogonadism. The "making a bigger pie" concept continues to drive the efforts of the AndroGel DTC Enterprise to this day. Thus, Defendants engaged in the DTC advertising to mass market AndroGel for Andropause, and for supposedly related ailments such as osteoporosis, sexual dysfunction, and depression, in male patients with both normal *and* abnormal testosterone levels, with *and* without clinical symptoms.

316. As part of the effort to drive "Andropause" prescribing activity, the AbbVie Defendants in 2005 purchased up to 40,000 subscriptions of Golf Digest Magazine to place in physician waiting rooms, with several-page AndroGel-affixed cover wraps. With a median readership age of fifty-one (51) that is 94% male, the AbbVie Defendants considered Golf Digest

"a consumer magazine that reaches the AndroGel target demographic." The target demographic, of course, was middle-aged to elderly men, the vast majority of whom did not suffer from hypogonadism.

317. More recently, the AbbVie Defendants' Marketing Department in conjunction with two medical vendor associates, Digitas Health and AbelsonTaylor, highlighted what it termed a "Drive for Five" award-winning campaign in order to drive prescriptions for AndroGel. The Drive for Five campaign urges men to know their "T" levels, in addition to lipids, blood pressure, blood sugars, and PSA numbers. On Defendant AbbVie's website, www.driveforfive.com, is an animated manual transmission shifter that shifts from "high cholesterol" (first gear) to "high blood pressure" (second gear) to "high blood sugar" (third gear) to "high PSA" (fourth gear), and finally, to "low testosterone" (fifth gear). Of course, this is simply another manifestation of Defendants' strategy suggesting that low testosterone/hypogonadism is a condition as prevalent as high blood pressure, and to drive patients to ask for notoriously unreliable testosterone screening and testing, with the intention that it lead to an AndroGel prescription.

318. An article discussing AbbVie's receipt of an award from Medical Marketing & Media for "Large Pharma Marketing Team of the Year: AndroGel," (titled *Vim, Vigor and Sales Drive*) quoted Frank Jaeger, director of Men's Health, AbbVie: "Hypogonadism affects about 14 million men in the US alone, but less than 10% are currently being treated for the condition … We felt something needed to be done to educate men about this condition." The article also states that "[i]t didn't hurt [AbbVie's sales efforts] that baby-boomers have proven less than shy about availing themselves of any product that they believe will increase their quality of life." The AbbVie Defendants merely had to instill that belief for AndroGel to thrive. Of course, the

www.driveforfive.com website links to Defendant AbbVie's www.isitlowT.com website, to encourage patients to take the misleading and over inclusive ADAM screening questionnaire.

319. Despite the fact that the ADAM or IsItLowT? Quiz is palpably false and misleading, the AbbVie Defendants still centrally feature the quiz on its websites, including the AndroGel product website (http://www.AndroGel.com/low-testosterone-symptoms-quiz (last visited June 13, 2014)), as well as an independent AbbVie-sponsored website with the web address, www.isitlowt.com.

VII. AUXILIUM FRAUDULENT MARKETING OF TESTIM AND TESTOPEL

A. Auxilium's Testim and Testopel Peer Selling Enterprise

320. In order to carry out the Testim and Testopel Peer Selling Enterprise, Defendant Auxilium associated with numerous marketing organizations.

a. Testim Peer Selling Association with GSK

321. In 2012, Auxilium and GSK entered into a co-promotion agreement relating to Testim. The co-promotion began shortly thereafter and continued until the parties mutually agreed to terminate the arrangement in late July 2013.

322. Under the terms of the agreement, "if net sales of Testim exceed a baseline established under the GSK Agreement, [Auxilium] pay[s] GSK a promotional payment equal to a percentage of incremental net sales above that established baseline" In other words, through this profit-share agreement, Auxilium incentivized GSK to aggressively promote Testim, including for off-label and label expanding uses.

323. GSK has a long history of aggressively promoting its own products for off-label uses. For example, as recently as June 2014, GSK paid $105 million to settle claims that it promoted numerous of its drugs illegally, including for off-label uses. Strikingly, under the terms

of the settlement, GSK agreed to reform its marketing practices and refrain from disseminating information relating to the off-label uses of its drugs.

324. In 2012, GSK paid $3 billion to settle investigations by the U.S. Department of Justice related to allegations that GSK marketed Paxil for off-label use in children and marketed Wellbutrin for weight loss and substance abuse, among other claims.

325. GSK even has a documented history of promoting TRT drugs off-label prior to being engaged by Defendant Auxilium. As discussed in more detail below, SmithKline Beecham, which merged with Glaxo Wellcome to become GSK, had been retained to promote the TRT drug Androderm, which received FDA approval in September of 1995. Concerned with GSK's rampant off-label promotion of Androderm, the FDA's DDMAC sent a warning letter to GSK in November of 1998 in relation to a "Promotional Dear Doctor Letter" that was "written on SKB letterhead and signed by SKB representatives" that was "misleading because it suggests that Androderm is safe and effective for treating non-insulin dependent diabetes mellitus (NIDDM) when such has not been demonstrated by adequate and well-controlled clinical trials." The letter had claimed that "testosterone supplementation … may result in significant improvements in insulin sensitivity, thereby potentially improving glucose control."

326. The engagement of GSK in the co-promotion agreement, including GSK's vast sales force, allowed Auxilium to expand its access to prescribing physicians. In 2012, Auxilium "[c]arefully targeted sales and marketing efforts aimed as the most productive segment of the TRT market – 17,000 high volume prescribing physicians who account for approximately 51% of all gel TRT prescriptions." *See* Auxilium 2012 Annual Report ("Fully Maximize Value of Current Portfolio") at 42.

b. ***Testim Peer Selling Enterprise Association with Lathian Health***

327. In 2006, Auxilium retained Lathian Health ("Lathian"), a provider of pharmaceutical marketing services and technology-based sales solutions, to perform Peer Selling "ePromotion" and "eBrand Messaging" programs on behalf of Auxilium with respect to the Testim product.

328. Lathian recruited one hundred fifty (150) physicians to participate in an on-line branding campaign for Testim, which then enabled Auxilium's Testim branding and marketing teams to select a broader promotional campaign directed towards an expanded number of physicians for the purpose of increasing and promoting off-label prescriptions for the Testim product.

329. The goal of the "ePromotion" program was to use Lathian's "Virtual Detailing" to increase physician prescribing habits with respect to the Testim product among a group of 25,000 targeted physicians by retaining a respected physician to relate a marketing narrative for a pharmaceutical product. As related on Lathian's website, Lathian delivers "[c]reative narratives using KOL [physician key opinion leaders] and interactive data review [that] are carefully crafted to deliver unique learning experiences …."

330. At the corporate level, the "ePromotion" strategic initiative was undertaken to improve Auxilium's "top-line" revenues and "bottom-line" earnings generated from sales of the Testim product, and to increase market share of Testim in the TRT drug space.

331. An IMS Health Study of Lathian's Virtual Detailing program for Testim revealed that it was highly successful in influencing prescribing behavior. Several metrics of the program's success were related in a Business Wire article: "[f]or every $1 that was invested in the programs, Testim gained $4.45 in revenue from increased sales"; "[d]uring the post-test period, test physicians prescribed (TRx) 38.9 percent more of the brand compared to control

physicians"; "[p]hysician penetration increased by a differential of +4.6 share points between the two groups, which was statistically significant"; and "[t]he brand's TRxs increased as physician participation increased, with the maximum increases seen with participants completing all three waves of the Virtual Detailing program." David Keats, an Auxilium Testim product manager, agreed with the study results that the eDetailing program had a significant impact on physician prescribing habits. As stated by Mr. Keats, "Lathian came to the table with a broad range of ideas and concepts, which quickly demonstrated they understand what works, what doesn't and what is truly a new front for sharing key messages. In all areas – content development, account management, recruitment and reporting – we are quite satisfied." The "broad" range of "key message" ideas included off-label or label expanding promotion of Testim.

332. The "ePromotion" strategic initiative relied upon in promoting Testim to physicians off-label for the treatment of age-related declines in testosterone levels and age-related symptoms in men, encouraged off-label prescribing and label expansion with respect to the Testim product's clinical uses.

B. Auxilium's Testim and Testopel Publication Enterprise

333. In order to carry out their Testim and Testopel Publication Enterprise, Defendant Auxilium and its associates exercised close control to ensure that their off-label marketing messages were prominently included in seemingly unbiased clinical studies which were in fact the opposite.

334. Auxilium regularly engaged ghostwriters to repackage its marketing message for Testim and whose work it then touted as the work of independent clinical researchers. For example, Robert Withers of WithersWorks, bills himself as a "pharma/healthcare writer" and states that his "experience and skills are broadened by former work as a medical ghostwriter …."

Mr. Withers (who holds an MFA in Film and a B.A. in Art History) lists Testim as among his clients.

335. A 2012 Testim study is exemplary of Auxilium's Publication Enterprise. The study listed five (5) authors, four (4) of whom are physician participants in the Peer Selling Enterprise with Auxilium speaking and consulting relationships. The fifth author is an Auxilium employee. Bhattacharya et al., *Testosterone Replacement Therapy Among Elderly Males: The Testim Registry in the U.S. (TRiUS)*, 7 J. Clin. Interv. Aging 321-330 (2012). After concluding that "Hypogonadal men [aged 65 and above] showed significant benefit from TRT" and that "TRT was well tolerated in older patients[,]" the authors disclose in the "Acknowledgments" Section that "The authors thank Lynanne McGuire, PhD, of MedVal Scientific Information Services, LLC, for providing medical writing and editorial assistance." Buried in a separate footnote is an apparent concession that MedVal provided more than just "assistance" to the "authors": "All authors contributed equally and were involved in … drafting ***and/or*** critically revising the manuscript. All authors reviewed the final manuscript and gave approval for submission." In other words, the authors (one of which was an Auxilium employee) rubber-stamped their credentialed names to a paper drafted by a medical writing company paid for by Auxilium.

336. Another similar example is an article featuring largely the same authorship, both named and unnamed. The article promotes TRT use among opioid users regardless of whether they suffer from hypogonadism. G. Blick, et al., *Testosterone Replacement Therapy Outcomes Among Opioid Users: The Testim Registry in the United States (TRiUS)*, 13 Pain Medicine 688-98 (May 2012), http://www.ncbi.nlm.nih.gov/pubmed/22536837 (last checked on September 22, 2014). The authors include internal Auxilium-employee authors Harvey Kushner and Dat

Nguyen. Once again, the authors disclose their extensive ties to Auxilium, and "acknowledge" ghostwriter "Sherri Jones, PharmD of MedVal Scientific Information Services, LLC for providing medical writing and editorial assistance."

337. Another example is a Testopel article with six (6) listed authors, at least four (4) of whom are participants in the Auxilium Peer Selling Enterprise. McCullough, et al., *A Multi-Institutional Observational Study of Testosterone Levels After Testosterone Pellet (Testopel) Insertion*, 9 J. of Sexual Medicine 594-601 (2012). The article extols the virtues of Testopel, which is not surprising considering the authors have received grants and personal fees from Auxilium and Endo, among others.

338. In another original article published in the International Journal of Impotence Research, several Auxilium Peer Selling Enterprise physician participants argued that "Changing from AndroGel to Testim offers hypogonadal men the potential for improved clinical and biochemical responsiveness" among the "significant proportion of men … [who] have a suboptimal response to the initial brand of testosterone gel prescribed." E.D. Grober, et al., *Efficacy of Changing Testosterone Gel Preparations (AndroGel or Testim) Among Suboptimally Responsive Hypogonadal Men*, 20 Int'l J. of Impotence Research 213-217 (2008). Despite the fact that every listed author disclosed financial ties to Auxilium for speaking, consulting, and research, the lone conflicts of interest disclosure reads in its entirety: "There are no sources of funding ***directly*** related to this research to disclose." (emphasis added).

339. As an example of how such studies distort the public's perception of a drug, a Livestrong.com article (a popular resource for patients) on "Effects of Testosterone Cream" cites "a study published in a 2005 issue of 'Reviews in Urology' … by Dr. John D. Dean of the Salisbury Clinic in the U.K." for the results that TRT "found a significant increase in body

composition after treatment. Bone mineral density improved, and there was an increase in lean body mass as well as a decrease in fat mass." The Livestrong.com article (likely unintentionally) omitted that the other three (3) authors of the review article were Auxilium employees, that the article was sponsored by Auxilium, and that the copyright was owned by MedReviews, LLC, which states on its website that it was "Founded to disseminate credible scientific information via three key publications … Reviews in Urology, we have grown into a full-service medical communications agency, providing content development and strategic marketing management services to our clients." In other words, Livestrong.com cited a promotional paper masquerading as credible science. The article, of course, touted testosterone therapy for a host of off-label uses.

C. The Testim and Testopel DTC Enterprise

340. Auxilium engaged in DTC marketing, promotional, and comprehensive educational campaigns through a variety of educational, advertising, and informational multimedia platforms, including Internet-based dedicated "Low T," "Testim" and "Testopel" websites.

a. The Testim DTC Enterprise Association with Heartbeat Ideas

341. During or prior to 2010, Heartbeat Ideas, a full service digital marketing agency, together with and on behalf of Auxilium, initiated Auxilium's DTC "Low Testosterone Therapy with Testim" advertising campaign.

342. In 2011, Auxilium's "Low Testosterone Therapy with Testim" advertising campaign received awards from the Pharmaceutical Executive's Ad Stars and the DTC Perspectives National Ad Awards. *See Heartbeat and Auxilium Work Recognized by Ad Stars and DTC National*. Business Wire. (May 24, 2011).

343. On October 13, 2011, Auxilium announced that the company's low testosterone awareness campaign, "Low T Facts" was recognized as the "Best Interactive Initiative for Consumers" at the 2011 Medical Marketing & Media (MM&M) Awards. *See New Release-Investors-Auxilium. Low T Facts Recognized as "Best Interactive Initiative for Consumers*, PR Newswire via COMTEX (Oct. 13, 2011).

344. In their award submission for the "Low T Facts" campaign (*see* http://www2.heartbeatideas.com/auxilium/lowtfacts.html), which was undertaken on behalf of and for the benefit of Auxilium, Heartbeat Ideas stated:

> Award Submission – Low T Facts Online Media Campaign
>
> *Unbranded Rich Media Banners, LowTFacts.com Microsite, Testim.com Website*
>
> Low testosterone, medically known as hypogonadism, occurs when a man doesn't produce enough of the hormone testosterone. Up to 13 million men in the United States may have low testosterone, although many don't know they are affected. That's because low testosterone produces symptoms like reduced sexual function, desire and performance, low energy or fatigue, bad mood or poor concentration, reduced muscle mass/strength and increased body fat, which are often attributed to other conditions.
>
> The target audience for this campaign was 50-64 year old men who have not been diagnosed with low testosterone, but have the symptoms of low testosterone. This group includes 20.5 million undiagnosed men (currently, 22.7 men in this age group suffer from low testosterone, but only 2.2M (10%) are being treated).
>
> Since low testosterone can be hard to detect and a sensitive topic to discuss, our goal was to help men recognize their symptoms and encourage them to seek treatment for the real problem. The result was an online media campaign featuring broadcast quality commercials that dispelled common misunderstandings of low testosterone symptoms, and increased awareness of the condition and its treatment, all while keeping a sense of humor about the potentially sensitive medical issue. We achieved this through gently humorous unbranded videos featured in unbranded ads that drove users to www.lowtfacts.com for additional information on

symptoms and a branded treatment solution.

345. As is clear from a screen-shot of DTC bannering, the messaging was clearly to support the promotion of label expanding utilization of Testim in aging men. The banners featured the claim that "Low Testosterone Affects up to 1 in 3 Men Over Age 45" and asked the question: "Is Your Sex Drive Not What It Used To Be?" The implication, of course, was that Testim could be used off-label to treat erectile dysfunction or decreased libido. As HeartBeat Ideas stated on its website, its challenge was to "[s]eparate low testosterone from erectile dysfunction" and to "[d]o it *delicately*." In other words, HeartBeat Ideas sought to promote the understanding that sexual dysfunction in men could be the result of low testosterone, as opposed to other conditions which might cause erectile dysfunction. Other DTC banners suggested that "depressed mood may be signs of low testosterone."

346. If the DTC materials were not clear that Defendants, with the assistance of HeartBeat Ideas, were suggesting Testim off-label use, the screenshot of the Testim.com website reproduced by HeartBeat Ideas as part of its portfolio is explicit in its promotion of off-label use for a number of conditions (erectile dysfunction, osteoporosis, obesity). The screenshot of the website states: "With Testim, you may experience: SUSTAINED symptom improvement with continued use; IMPROVED sexual function, desire, and performance; INCREASED muscle mass and bone density; DECREASED fat mass." (http://www.heartbeatideas.com/work.php).

347. None of the DTC materials developed by HeartBeat Ideas disclosed or discussed any issues regarding the cardiovascular effects of Testim or testosterone use, despite the fact that several of these materials were developed after the Testim Barasia Study in frail and elderly men was halted by the study's drug safety review panel due to an excess of adverse cardiovascular events among Testim patients.

348. Auxilium and HeartBeat Ideas materially and deceptively misrepresented and mischaracterized the definition of hypogonadism.

349. Auxilium and HeartBeat Ideas materially and deceptively misrepresented Testim's safety and efficacy profile for any number of off-label uses.

b. ***The Testim and Testopel DTC Enterprise Association with Transit Creative Brand Design Group***

350. The Auxilium Defendants retained the "Transit Creative Brand Design Group" to formulate and design a DTC marketing strategy and marketing plan with respect to the Testim and Testopel products.

351. The "Transit Creative Brand Design Group" formulated a DTC marketing plan that provided men with educational and medical informational materials about the Testim product.

352. The "Transit Creative Brand Design Group" DTC marketing plan included a celebrity testimonial and endorsement from United States Professional Golf Association (PGA) golfer Shaun Micheel, who the endorsement stated had been "successfully" treated for "Low T" with Testim by providing "[m]ore support … to help him be himself." The testimonial was obtained with the assistance of vendor participant MCS Healthcare Public Relations.

353. The website featuring "The Shaun Micheel Story" and "Shaun's experience with Low T" offered consumers and patients "Education about Low T;" an "Interactive ADAM Questionnaire;" "Comprehensive disease-state information;" and a "Physician Finder" service to assist patients in finding physicians who were prescribing Testim therapy for the treatment of "Low T."

354. Auxilium's "Integrative ADAM Questionnaire" referenced on the Shaun Micheel endorsement website for the Testim product invited consumers to visit a website designed to

self-screen and self-assess "Low T" signs and symptom patterns. The website provided criteria for the diagnosis of "Low T," and a scoring system for signs and symptoms as they relate to the diagnosis of "Low T." Shaun Micheel later publicized that he underwent heart surgery, at age forty-five (45), and has since disappeared from Defendant Auxilium's DTC campaign.

355. The ADAM Questionnaire was largely the same questionnaire used by the AndroGel Defendants. However, in 2010, an article was published in the International Journal of Impotence Research by several authors, including two (2) (Drs. Khera and Lipshultz) who disclosed that they were paid speakers for Auxilium. The article proposed a modified "quantitative" ADAM Questionnaire (qADAM), which instead of posing simple "yes" or "no" questions, instead asked screened patients to answer the questions on a scale. For example, the ADAM Questionnaire asked, "Are you falling asleep after dinner?" The qADAM asks, "How often do you fall asleep after dinner?", with answers given on a 1-5 scale ranging from "never" to "every night."

356. From a marketing perspective, it can be safely assumed that all people sometimes fall asleep after dinner, and yet many of these people would respond "no" when given only "yes" or "no" options. By allowing for a quantification of such a vaguely phrased question, Defendants anticipated that screened patients who would have responded "no" to the ADAM question might concede that sometimes they do fall asleep after dinner. The qADAM was thus likely to generate even more false positives of "Low T" than the original ADAM questionnaire.

357. Under either the ADAM or qADAM Questionnaires, the "signs" and "symptoms" Defendants sought to link to low testosterone are not approved clinical indications for androgen therapy, including with the Testim and Testopel products.

358. The "Interactive ADAM Questionnaire" further provided a mechanism for a consumer or patient, without a physician intermediary, "[t]o order a home-saliva test" for further self-diagnostic testing for "Low T."

359. The Shaun Micheel endorsement website afforded consumers a means to be referred to or gain access to a physician known by Auxilium to treat "Low T" and to prescribe the Testim product, with Auxilium serving as the referral.

360. Both the Endocrine Society and the European Association of Urology have recommended against using "Low T"-type quizzes, screeners, and self-assessment questions because these methods are known to be unreliable and over-inclusive.

361. Auxilium knowingly promoted Testim and Testopel to physicians as being a treatment for the "conditions" set forth in the "Interactive ADAM Questionnaire." Those "conditions" are mostly for off-label and/or label expanding use of Testim and Testopel.

362. At all times material hereto, Auxilium engaged men in the "The Level Up Plan" on its Testim website, which was undertaken to drive men to seek "Low T" treatment with "off-label" prescriptions for Testim.

363. The "The Level Up Plan" solicited Protected Health Information (PHI) from patients, including current medication profiles ("I am currently being treated with Testim"); and, whether patients were currently diagnosed with "Low T" ("When do you intend to seek treatment for Low T?"). Notably, the preliminary question of whether the patient actually suffered from hypogonadism was not asked.

364. Auxilium knew that physician prescription practices with respect to the Testim and Testopel products were heavily influenced by and driven by consumer demand for the testosterone treatment.

365. "The Level Up Plan" acknowledged the central and pivotal role of consumer choice and product demand with respect to Testim treatment and usage, and the fact that consumer acceptance of Testim treatment was a key driver of product sales, revenue and earnings growth, and prescription demand.

366. The Auxilium Defendants also retained the "Transit Creative Brand Design Group" to redesign its Testopel website and to produce video materials to promote Testopel.

367. The Transit Creative Brand Design Group's website includes a Testopel portfolio page that succinctly describes its efforts on behalf of the Auxilium Defendants, "When you're the little guy in a field of giants, you've got to be smart. Rather than expend limited resources trying to go head-to-head with larger players, [the Auxilium Defendants] chose to do one thing and do it well: get patients with low testosterone on therapy and keep them there. Transit helped show how easily Testopel pellets can do that."

368. Overlapping with the Testim and Testopel Peer Selling Enterprise, the "Transit Creative Brand Design Group" also acknowledged part of its mission with the Testopel account was to promote Testopel to those within the medical profession, and, thanks to its video materials and website redesign, "10,000 doctors now know about Testopel."

369. In 2010, the FDA sent a warning letter to the Auxilium Defendants concerning its promotion of Testopel.

370. The FDA was concerned about certain promotional materials relating to Testopel, including a sales aid and certain webpages and video materials available at www.testopel.com.

371. The FDA noted the materials "promote unapproved uses of Testopel, omit and minimize important risk information associated with Testopel, broaden the indication of Testopel, overstate the efficacy of Testopel, present unsubstantiated superiority claims for

Testopel, omit material facts, present misleading convenience claims, present an unapproved dosing regimen for Testopel, and/or present other unsubstantiated claims about Testopel."

372. For example, the FDA criticized comments made by Dr. Abraham Morgentaler in a video on the Testopel website. In the video, Dr. Morgentaler, asking physicians to rely on his authority as a sexual medicine specialist, told them that when his patients started treatment for low T, "Their strength may improve, their workouts at the gym may get better, they start chasing their wives around the room a little bit - they just feel like guys again."

373. With regards to Dr. Morgentaler's sales pitch, the FDA stated the "totality of these claims misleadingly implies that Testopel can be used to treat sexual dysfunction" and "misleadingly implies that Testopel has a positive impact on the enhancement of athletic performance."

374. The FDA also noted its serious concern that the video omitted or minimized the "serious risks" associated with the use of Testopel. Specifically, the video materials failed "to convey any risks specific to Testopel during the efficacy presentation." The only risk information presented was relegated to the end of the video, "in small print type in single-spaced paragraph format, with no accompanying audio presentation, and it appears on the screen for less than ten seconds, which does not allow adequate time for viewers to read this information."

375. Further, although the video materials presented some of the contraindications associated with Testopel, the FDA was distressed the materials "completely omit[ted] the most serious and important warnings," precautions, and adverse reactions.

376. Although the Testopel website has since been edited and Dr. Morgentaler's video is no longer available, the Testopel website is still misleading and omits and minimizes serious risk information.

377. For example, the Testopel website explicitly equates hypogonadism with low testosterone by stating, "Low testosterone (Low T), also known as hypogonadism, occurs when a man's body produces little or no testosterone and has associated signs and symptoms."

378. The Testopel website adds that studies have found that 1 in 3 men suffer from Low T. This "statistic" (likely pulled from the Mulligan HIM Study developed by the AbbVie Defendants) misleadingly implies that a third of the male population suffers from hypogonadism, which significantly overstates the prevalence of this rare condition.

379. The Testopel website also lists a plethora of "signs and symptoms" of low T, including decreased sex drive, decreased energy, decreased motivation, decreased self confidence, feeling sad or blue, poor concentration or memory, sleep disturbance, reduced muscle bulk and strength, increased body fat, and decline in physical performance.

c. ***The Testim DTC Enterprise Association with "e-tractions"***

380. In 2010, Auxilium engaged the marketing services of "e-tractions," a web-based marketing solutions provider, to optimize the web-based Testim DTC marketing campaign.

381. In 2010, "e-tractions" published its "Case Study of Testim"[3] as follows:

> THE BRAND: TESTIM
>
> TESTIM, manufactured and marketed by Auxilium, is a prescription medicine used to treat hypogonadism, a medical condition that occurs when the body does not make enough testosterone. There are an estimated five million American men living with symptoms of low testosterone.
>
> THE CHALLENGE
>
> The challenge for e-tractions and the TESTIM brand team was to increase overall brand awareness. Testosterone replacement therapy is a category with very low awareness and there had been no significant investment by TESTIM or its competitor, AndroGel®.

[3] Case Study of Testim at http://peerengage.com/downloads/TESTIM_CS.pdf.

THE SOLUTION

The TESTIM brand team turned to e-tractions to develop and manage an online marketing campaign designed to create awareness of TESTIM and stimulate demand for the product. Campaign elements were tracked and measured using EnterAct™, the e-tractions technology platform.

KEY PROGRAM FEATURES

The program components developed by e-tractions included:

- Co-registration
- An engaging interactive
- Relationship marketing emails

There were four objectives for the campaign. The first was to drive traffic to www.testim.com in order to create greater awareness and understanding of hypogonadism and TESTIM in particular. The second was to encourage registrant to download a rebate coupon to stimulate demand. The third was to collect names and email addresses of registrants so that TESTIM could communicate with registrants through permission-based emails on a regular basis. And lastly, the goal was to use the registration as a means to better understand the demographic and behavioral profile of potential TESTIM patients. e-tractions developed an informative and engaging game, “Fact or Fiction”, designed to provide people with a better understanding of hypogonadism and TESTIM as a possible therapy.

RESULTS

The nine-month online marketing campaign generated a database of over 260,000 names and email addresses of men who gave permission for TESTIM to communicate with them via email. Both traffic to testim.com and registrations on the site increased significantly, with more than 30% of those who responded to the online advertising downloading a TESTIM rebate offer.

Emails segmented by condition, such as erectile dysfunction and type 2 diabetes, enjoyed open rates averaging more than 6%, a strong performance as compared to industry norms. As important as the strong open rates, TESTIM gathered valuable data to assist future marketing efforts. Based on registration information, the average age of prospects was 10 years younger than TESTIM had

> originally projected and over 60% of registrants claimed to have type 2 diabetes.
>
> Contact Dan Keefe at (781) 276-1800 x27 or dkeefe@e-tractions.com

382. As stated by e-tractions itself in the above-reproduced text, among the primary targets for Testim DTC marketing were patients with erectile dysfunction and type 2 diabetes, both off-label conditions for which Testim use was not shown to be safe or effective. Notably, patients with erectile dysfunction and type 2 diabetes are typically at greater risk of cardiovascular disease, and therefore a drug's cardiovascular safety profile would have been particularly important to physicians treating such patients.

383. The message provided by www.testim.com intended "to create greater awareness and understanding of hypogonadism and TESTIM in particular" and to "stimulate demand for the product" was knowingly false, inaccurate, deceptive, and misleading with respect to the information offered, and willfully sought to conflate the diagnosis of hypogonadism with the diagnosis of "Low T" or age-related declines in testosterone levels or age-related symptoms in men, among other inappropriate off-label uses.

d. ***The Testopel DTC and Peer Selling Enterprise with TRG Communications, LLC***

384. Defendant Auxilium also engaged vendor participant TRG Communications, LLC to develop a "Core sales aid, patient educations materials, and posters."

385. The "Concept" was to "TURN IT ON" with Testopel, and TRG Communications explained that "[w]e used the universal 'On' symbol (as seen on a multitude of devices used today) as highlight recognizable iconography to denote the patient being 'Powered On' for 3-6 months once TESTOPEL® is placed."

386. Defendant Auxilium and TRG sought to link Testopel with symptom treatment for fatigue and to give middle-aged men a boost of energy. The materials are highly suggestive of off-label use.

VIII. DEFENDANT ELI LILLY'S FRAUDULENT MARKETING OF AXIRON

387. Defendant Eli Lilly launched Axiron in the first quarter of 2011, after purchasing an exclusive license to commercialize the product from Australia-based Acrux. According to the terms of the license, Lilly agreed to pay $50 million upfront, an additional $87 million upon FDA approval of Axiron, and $195 million in potential post-approval milestones.

388. Defendant Lilly's press release announcing the deal made it clear that Lilly intended to promote Axiron for off-label and label expanding uses. In the "About Hypogonadism" section, Defendant Lilly explained: "Testosterone deficiency in men (hypogonadism) is associated with a number of clinical problems. It has been estimated that up to 39% of men over 45 years of age may have testosterone levels below the normal healthy range [citing the Mulligan HIM Study, *supra*]. However, in the majority of men this remains undiagnosed, with approximately 10% of those with the condition receiving treatment." Even before Axiron's approval, Defendant Lilly sought to link age-appropriate testosterone levels to other co-morbidities and to suggest testosterone treatment was appropriate for nearly half of the male population over the age of 45. These statements echoed (and even cited) the decade or so of disease mongering pioneered by the AbbVie Defendants.

389. Defendant Lilly's Peer Selling Enterprise, Publication Enterprise, and DTC Enterprise were similar in structure and function to those of the AbbVie Defendants and of Auxilium, described above. Defendant Lilly has poured significant monies into its Axiron commercialization efforts. According to a 2014 report by Encuity Research, the top six branded

TRT products combined to spend a total of $282 million on promotional efforts in 2013, up from just $55 million in 2009. Lilly's Axiron led the way, even surpassing the AbbVie Defendants' AndroGel promotion efforts; Lilly spent almost $122 million on Axiron promotion in 2013, spread among the Peer Selling, Publication, and DTC Enterprises. This is despite only achieving $178 million in sales in 2013. Defendant Lilly clearly sees Axiron as a long-term project and made a large bet on its success.

390. The consensus among both observers (such as Encuity) and participants (such as Acrux) is that "[t]he ramp-up of promotional activity is clearly having its desired effect." Fueled by Lilly's success promoting Axiron, Acrux's stock soared 63% in one month alone in July 2014.

A. The Axiron Peer Selling Enterprise

391. When Defendant Lilly entered the TRT market in Q1 2011 with Axiron, the testosterone market was already nearing $2 billion total in annual sales. In other words, Lilly entered a mature market. This did not stop Defendant Lilly from adopting the AbbVie Defendants' philosophy of "making a bigger pie" by vigorously promoting the disease state and alleged off-label comorbidities Axiron was supposedly safe and effective in treating.

392. Defendant Lilly's Peer Selling Enterprise centered on (through vendor participants) hosting numerous events where doctors who had been trained and/or approved by Defendant Lilly would falsely oversell the efficacy and safety of Axiron and provide favorable information on the off-label use of Axiron, often under conditions where physicians were compensated for attending the presentation. Defendant Lilly has funded (and continues to fund) scores of such events.

393. Defendant Lilly created and controlled a Peer Selling Enterprise composed of medical marketing firms and dozens of physicians who routinely promoted Axiron to other physicians in venues all across the country. Defendant Lilly maintained sufficient control over the Axiron Peer Selling Enterprise to select and approve the content of the programs and the physician participants that would deliver the off-label messages. Physicians who were not receptive to promoting Axiron for the off-label uses were not considered for inclusion in the Axiron Peer Selling Enterprise. The physicians (mostly primary care physicians) who attended these events were deceived into thinking that the events were educational in nature and independent from the control of Defendant Lilly.

394. Recruiting many of its physician participants from the rosters already developed by the AbbVie Defendants and Auxilium, as well as developing its own, Defendant Lilly promoted Axiron for off-label and label expanding uses through these physician speakers. Defendant Lilly has paid extravagant sums of money to leading urologists and endocrinologists in exchange for their publicized support of Axiron. For example, Dr. Irwin Goldstein, President and Director of the San Diego-based Institute for Sexual Medicine and a Lilly physician participant, has been paid at least $122,000 by Defendant Lilly in the past three (3) years for travel, speaking, meals, and consulting. Dr. L. Dean Knoll, of Urology Associates Nashville, has been paid over $200,000 by Defendant Lilly in the past several years for consulting, speaking, meals, travel, and “other.” Dr. Culley C. Carson III, who is the Rhodes Distinguished Professor of Urology at UNC-Chapel Hill and a physician participant in Defendant Lilly’s Peer Selling Enterprise, has been paid a comparatively modest $55,000 by Defendant Lilly for travel, consulting, meals, speaking, and “other” since 2009.

395. For all of the money that has been disclosed, many of Lilly's payments remain under the radar. As mentioned above and described in detail below, Defendant Lilly funnels millions of dollars per year toward so-called "educational programs" in the form of continuing medical education (CME) events. The events are remarkably homogenous both in content and in terms of the chosen faculty/speakers for such events. This is because these are pre-packaged programs prepared and paid for by Defendant Lilly, which then passes them off in the form of educational "grants" to disguise Lilly's role and payments to the physician lecturers.

396. Defendant Lilly's Grant Office, for example, states that it "provides grants and charitable contributions for healthcare profession education … programs in a variety of therapeutic areas." Those therapeutic areas more than often coincide with the products Lilly is promoting. Lilly only cagily acknowledges that "it is possible that the educational programs funded by the company through grants have discussed off-label uses of our products."

397. According to the 2013 Lilly Grant registry, Defendant Lilly expended approximately $2.75 million on so-called "Educational Programs" falling under the disease state "Urology – Hypogonadism" during the 2013 calendar year. This followed similar expenditures of approximately $2.3 million in 2012. Defendant Lilly expended tens of millions more on educational programs for supposed co-morbid diseases, such as erectile dysfunction, Alzheimer's, diabetes, etc., where off-label references to TRT or Axiron treatment might "possibly" have been discussed. The funding for these programs (and for the physician participants) was channeled through dozens of Axiron Peer Selling Enterprise vendor participants, some of which are detailed *supra*.

398. The Axiron Peer Selling Enterprise employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy

of Axiron for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Axiron for both approved indications and for a variety of off-label uses; (c) deliberately concealing negative findings or the absence of positive findings relating to the off-label uses of Axiron; (d) wrongfully and illegally compensating physicians for causing the prescribing of Axiron; (e) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Axiron for both on-label and off-label uses, and then disseminating copies of such studies by the thousands; (f) intentionally misrepresenting and concealing Defendant Lilly's role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Axiron to off-label markets; and (g) intentionally misrepresenting and concealing the financial ties between Defendant Lilly and other participants in the Enterprises.

399. For example, AccelMed, LLC is the first-listed vendor on Defendant Lilly's 2013 Grant Registry, having received nearly $450,000 for three hypogonadism-related programs in 2013. As cryptically conceded on AccelMed's website, the focus of such programs was not purely educational: "We understand the sensitive balance between science, adult learning, and tactical preferences that can turn educational challenges into opportunities." Of course, the "tactical preferences" and "opportunities" related to the commercialization efforts by AccelMed's pharmaceutical clients for their products, which included Eli Lilly for its Axiron product.

400. Unsurprisingly, the faculty presenting these AccelMed programs include physician participants in the Axiron Peer Selling Enterprise who presented at these and a multitude of other Lilly-sponsored "educational programs." For example, in a 2014 AccelMed

Program titled "Practical Primary Care Strategies for Diagnosing and Managing Hypogonadism in Men – Best Practices to Improve Patient Outcomes," the two faculty lecturers were Dr. Martin Miner and Dr. Matt T. Rosenberg, both of whom are Axiron physician participants and are frequently on the roster of Lilly lecturers at such events. Dr. Rosenberg disclosed serving as a consultant for Lilly (among other pharmaceutical companies). Dr. Miner disclosed such arrangements with AbbVie and Endo, but not for Eli Lilly, which is surprising since Dr. Miner has disclosed elsewhere that he served on Eli Lilly's advisory board.

401. Defendant Lilly expected that Dr. Miner and Dr. Rosenberg would present on the off-label uses of TRT drugs, including Axiron. Indeed, the "Program Overview" of this CME-accredited program states: "Testosterone deficiency is associated with a well-documented increase in risk of mortality and detrimental effects on quality of life: loss of energy and libido, erectile dysfunction (ED), joint pain and stiffness, memory impairment, irritability, and depression. In spite of this, hypogonadism remains an under diagnosed syndrome that, with its links to age, obesity, type 2 diabetes mellitus (T2DM), and metabolic syndromes, is becoming increasingly relevant."

402. Assuming that Dr. Miner and Dr. Rosenberg followed the "Program Overview" (as well as the script and slides prepared by Defendant Lilly and provided through AccelMed), it appears that the entire program centered on the off-label or label expanding uses of Axiron and TRT drugs. Furthermore, because the payments to Dr. Miner and Dr. Rosenberg were funneled by Defendant Lilly through AccelMed, they are not listed in the physician payment databases that are publicly available. For example, publicly available reports show Dr. Miner having only received a few thousand dollars in total from Defendant Lilly despite his participation in dozens of these CME lectures.

403. Despite the limited information that is publicly available concerning physician payments, the local Michigan press ran a story on Dr. Rosenberg titled "Jackson doctor gets big checks from drug companies." In the story, Dr. Rosenberg defended himself asserting, "I don't do promotional pieces … Everything I do is based on education." It just so happened, however, that the content of Dr. Rosenberg's lecture mirrored Defendant Lilly's off-label promotional efforts of Axiron.

404. Similarly, Paradigm Medical Communications, LLC released in November 2013 a "Controversies in the Treatment of Male Hypogonadism" CME program "supported by an educational grant from Lilly" (the differences between Lilly "educational grants" and Lilly "independent educational grants" will be explored in discovery). The faculty included two prominent Lilly physician participants, Drs. Culley C. Carson and Mohit Khera. Dr. Carson is the Chief of Urology at UNC-Chapel Hill, but also serves on Lilly's advisory board and speaker's bureau. Dr. Carson has received hundred of thousands of dollars in payments from pharmaceutical companies, including Defendant Lilly. Dr. Khera is a Urology professor at Baylor, and is likewise on Lilly's speakers bureau and has been paid at least $75,000 by Defendant Lilly in the last three (3) years alone. Exemplifying how Defendant Lilly pre-packaged the scripts and slides for these events, the "Statement of Need" for this CME reads almost identically to the "Program Overview" in the previous CME discussed and presented by Dr. Miner and Dr. Rosenberg: "The condition is associated with symptoms including erectile dysfunction, loss of libido, and decreased energy levels, as well as comorbidities including obesity, decreased muscle mass, and potential cardiovascular complications, and can result in decreased vitality and a reduced quality of life. However, studies have shown that a significant proportion of men with hypogonadism go undiagnosed, or do not receive testosterone

replacement therapy due to either poor physician understanding of the benefits and safety of therapy or physicians' concerns of exacerbating other comorbid conditions."

405. The consistency of the message in all the Lilly-supported CME events is attributable to the fact that Lilly controlled the content of these packages as part of the Axiron Peer Selling Enterprise.

406. In another example, Defendant Lilly made two payments of $68,138 to vendor participant Med-IQ, LLC, for two runs of the program "Tackling Taboos: Optimizing Management of Men's Health Through Evidence-Based Care and Effective Patient Communication." The Faculty for each event were comprised of Dr. Rosenberg, who again disclosed extensive pharmaceutical ties, including to Defendant Lilly, and Dr. Steven A. Kaplan, who disclosed no potential conflicts. However, a review of ProPublica's DocDollars database reveals that Dr. Kaplan received hundreds of thousands of dollars from pharmaceutical companies, much of it through his consulting firm Solera Consulting, LLC. The slides for the Med-IQ CME, which are available online, begin their discussion of hypogonadism (after a discussion of erectile dysfunction) with the assertion that "Hypogonadism Is Underdiagnosed and Undertreated," relying on the Mulligan HIM Study funded and created by the AbbVie Defendants. The very next slide launches into off-label treatment suggestions; titled "Common Comorbidities of Hypogonadism," the slide listed comorbidities (along with odds ratios) such as obesity, diabetes, hypertension, hyperlipidemia, osteoporosis, and Asthma/COPD. The next slides focus on "Screening for Low Testosterone" and reproduce the ADAM questionnaire developed by the AbbVie Defendants as well as list the vague set of symptoms found on the www.Axiron.com website, including: Fatigue; Poor concentration; Sleep disturbance; Decreased muscle mass; Decreased erections; and Fragility fractures.

407. Dr. Louis Kuritzky, a Family Medicine Professor at University of Florida, declared in a Lilly-sponsored video that "replacement of testosterone is a very satisfying process." Defendant Eli Lilly paid almost $80,000 toward Dr. Kuritzky's seven (7) minute long video lecture delivered to the 2013 Men's Health World Congress, available on the Foundation for Men's Health website. Neither the website nor the video discloses Defendant Lilly's involvement. Dr. Kuritzky himself has received tens of thousands of dollars from Defendant Lilly and other pharmaceutical interests for consulting, speaking, and other services. In a four (4) minute lecture at the same Men's Health World Congress by Axiron physician participant Dr. Jed Kaminetsky, who is on the faculty at NYU Medical School, Dr. Kaminetsky attempted to address the association of TRT with prostate cancer growth by stating his opinion that TRT has "very little effect on the prostate." Neither the website nor the video discloses Defendant Lilly's involvement. Dr. Kaminetsky has been paid nearly $400,000 by Defendant Lilly alone since 2009 for research, consulting, speaking, travel, and meals.

408. Even some of the Peer Selling Enterprise materials had an air of DTC styling about them. At an American Association of Family Practitioners (AAFP) conference held in September 2013 in San Diego, Defendant Lilly (along with the AbbVie Defendants) gave $150,000 for the AAFP IDEAL "Hitting Below the Belt: Winning Strategies to Promote Men's Health" presentation. The series of panels depicted muscular and shirtless prizefighters and were boxing-themed. Several of the panels were TRT-related with titles such as "Go Toe to Toe with Testosterone Deficiency" and "Don't Get Caught Against the Ropes – Confirm the Diagnosis." In conjunction with the "Go Toe to Toe" panel, a "Clinical Pearl" of wisdom offered was to "[e]xplore the possibility of testosterone deficiency in certain middle-aged and older patients, such as those with type 2 diabetes and symptoms such as low libido and erectile dysfunction."

The identity of the presenter(s) for these TRT panel slides is unclear, but the message was classic off-label, andropausal promotion by Defendant Lilly and the AbbVie Defendants.

409. These CME-driven efforts were complemented with traditional detailing by Defendant Lilly's sales force. Lilly's sales force had been promoting Lilly's erectile dysfunction drug, Cialis, since 2003, and thus was well positioned to take on Axiron as well, given "Lilly's success with Cialis and the synergy between prescribing groups of Axiron and Cialis …." The sales force also arranged for the utilization of non-CME physician lecturers to whom Defendant Lilly's sales and marketing teams served as handlers. Defendant Lilly's sales force arranged less formal lectures and roundtables, publicized them to primary care physicians on details, drove the lecturers to the events, and provided them with scripts and slides for the events. As with the CME events, the lectures contained largely uniform messaging centering on: (1) the off-label uses for Axiron; (2) suggesting utilization of vague screening criteria such as the ADAM questionnaire or the list of symptoms on Axiron's website; and (3) disease fear mongering by suggesting that as little as 5% of men with "low T" were being treated. Eventually, physician speakers were also asked to make reassuring statements concerning cardiovascular safety of TRT and of Axiron.

B. <u>The Axiron Publication Enterprise</u>

410. Although Defendant Lilly, along with other TRT manufacturers, relied extensively on studies created largely by the AbbVie Defendants' Publication Enterprise, such as the Mulligan HIM Study, Defendant Lilly also sought to create the impression that the medical literature supported TRT and Axiron for off-label and label expanding uses.

411. As noted by Acrux, Defendant Lilly had undertaken clinical trials focusing largely on off-label usage of Axiron, "represent[ing] significant commitments by Lilly to expanding the

therapeutic indications for Axiron." Notably, Defendant Lilly has yet to request the FDA to expand the FDA-approved indications for Axiron. Whether the indications were FDA-approved mattered little to Defendant Lilly, so long as Axiron was being prescribed for these expanded indications.

412. Clinical trials undertaken by Lilly to support the "expanded" off-label use of Axiron included: "A trial for enhanced sex drive and energy levels"; "An ejaculatory dysfunction trial"; and "A trial for suboptimal responders to testosterone gels other than Axiron." Acrux was hopeful that other off-label pursuits would materialize, stating "[t]here is scope for testosterone use in other indications such as cachexia, which is the muscle wasting and weight loss that occurs in the later stages of cancer." Acrux also stated that "[e]xploratory clinical studies have been publicized investigating testosterone effects in Alzheimer's and Multiple Sclerosis. Another slide also listed chronic opioid use, renal disease, Type II Diabetes, and obesity as potentially ripe markets for testosterone. As did the AbbVie Defendants with AndroGel, Defendant Lilly used its Publication Enterprise to promote Axiron as snake oil.

413. Notably, all three (3) of the studies referenced above have been completed, but no trial results have been published and no publications have been released. In fact, the entries for all three trials on clinicaltrials.gov list Lilly alone as the "Study Sponsor," "Responsible Party," and "Investigator." No research physicians or collaborators are named. This is because Defendant Lilly is in control of all aspects of these studies, from inception and protocol creation to resulting publications.

414. Nevertheless, the efficacy study titled "A Study in Men with Low Testosterone to Measure the Effects of Testosterone Solution on Testosterone Levels, Sex Drive and Energy" bears the clinical trials identifying number NCT01816295, which is listed on the Urologic

Consultants of Southeastern Pennsylvania's website (http://www.urologicconsultsepa.com/handler.cfm?event=practice,template&cpid=26336) under clinical trials being conducted by that physician group. A sampling of the group's physicians reveals extensive pharmaceutical ties, with several physicians raking in hundreds of thousands of dollars from Eli Lilly and other pharmaceutical interests. For example, Dr. Phillip Ginsberg, seated front and center in the physician practice's team photo, has received nearly $250,000 in payments from Defendant Lilly and others since 2009 for meals, speaking, travel, consulting, and "combination." His colleague Dr. Richard Harkaway has been paid at least $365,000 by Defendant Lilly and others for speaking, travel, consulting, and meals since 2009. Dr. Laurence Belkoff has received over $200,000 from Defendant Lilly and other pharmaceutical interests for research and speaking since 2009. Once the (doubtless) favorable study results for this study are published, the study investigators and potential authors will be tapped by Defendant Lilly to ride the speaker circuit, proclaiming the study's positive results supporting Axiron's off-label use in exchange for handsome speaker payment fees. As is clear from the trial's clinicaltrials.gov entry, the trial is an Eli Lilly funded marketing venture designed, as stated by Acrux, for the purpose of "expanding the therapeutic indications for Axiron."

415. Even the studies supporting Defendant Lilly's NDA approval for Axiron followed the usual steps and involved the usual physician participants. For example, Defendant Lilly's www.Axironmd.com website (for healthcare professionals) states under the "Clinical Study" tab that "AXIRON was evaluated in a multicenter, open-label, 120-day trial of 155 men with hypogonadism." Defendant Lilly then relates some of the positive findings of the open-label study for potential prescribing physicians to cogitate on, while failing to disclose Defendant Lilly's and Acrux's extensive involvement in the study, including the resulting publication,

Wang *et al.*, Efficacy and safety of the 2% formulation of testosterone topical solution applied to the axillae in androgen-deficient men, J. Clin. Endocrinology (2011) 75:836-4. Dr. Christina Wang, whom Defendant Lilly recruited from the AbbVie Defendants' Peer Selling and Publication Enterprises, served as the lead author on the study. However, Dr. Wang's exact role in the study is unclear, as the study's clinicaltrials.gov entry lists the "Study Sponsor" as "Eli Lilly and Company," the "Responsible Party" as "Chief Medical Officer, Eli Lilly," the "Investigators" as "Eli Lilly and Company," and "Collaborators" as "None Provided." Two of Dr. Wang's co-authors were Acrux employees, and all of the authors (including Dr. Wang) with the exception of Dr. Niloufar Ilani, disclosed financial ties to Lilly, Acrux, or both. Dr. Wang herself disclosed a consulting relationship with Lilly and having received research grants from Acrux.

416. The "authors" went on to acknowledge several Lilly employees and employees of a ghostwriter company called "i3 Statprobe" for their purported "critical review of the manuscript." The company i3 Statprobe's website (www.i3global.com) redirects to inVentiv Health clinical (http://www.inventivhealthclinical.com/). Among the services provided by i3 Statprobe is "Phase IIB-III Clinical Trial Medical Writing" (http://www.inventivhealthclinical.com/phase-ii-iii-clinical-trials-medical-writing.htm). Defendant Lilly's study was a Phase III clinical trial. Described as providing a "full complement of medical writing services" through at least "160 writers, editors, and writing management staff[,]" the medical writers "provide all your documentation and writing needs." One of the medical writers "acknowledged" by Dr. Wang is Rich Pistolese, who holds a bachelor's degree in chemistry. This study was used to support Axiron's NDA and is featured prominently on Defendant Lilly's website and in the prescribing information.

417. Defendant Lilly employed many of the same tactics utilized by the other TRT defendants, including the AbbVie Defendants, in the formation of the Axiron Publication Enterprise. Study "authors" such as Dr. Wang exercised little control over the study's protocol and only had a superficial role in the dissemination of the study results and the creation of the medical literature pieces. Nevertheless, Dr. Wang's professional reputation was enhanced as the "lead author" of the study. Dr. Wang boasts on her faculty profile at UCLA School of Medicine's website that she "has authored over 250 peer-reviewed publications[.]" Dr. Wang was paid more than $250,000 in 2011 and 2012 by Defendant Lilly for her "research."

418. As part of Defendant Lilly's Publication Enterprise, Defendant Lilly created study protocols consistent with Defendant Lilly's intended Axiron marketing messages, funded these studies to completion, exercised total control over the decision to publish and the format and substance of the resulting medical journal articles, and paid largely through its vendor participants prominent physicians to lend their names for "authorship" of such articles in exchange for handsome payments. Defendant Lilly then masqueraded these predetermined study results, often ghostwritten by Defendant Lilly and its vendor participants, as credible science on its websites, through reprints distributed by Defendant Lilly's sales force to physicians, and through physician speakers as part of the Peer Selling Enterprise.

C. The Axiron DTC Enterprise

419. With the help of its vendor associates, Defendant Lilly has engaged in DTC advertising campaigns that fraudulently, misleadingly, and unlawfully concealed and minimized serious health risks associated with the use of Axiron, and promoted Axiron as safe and effective for unapproved off-label uses lacking scientific support.

420. Targeted DTC advertising of Axiron was designed to drive patients to ask their physicians for prescriptions of Axiron. Both branded Axiron and unbranded DTC disease state marketing were thus undertaken by Defendant Lilly and its associates, and were geared specifically toward expanding the definition of hypogonadism or branding "Low T" as a recognized disease state in need of treatment, preferably with Axiron.

421. Defendant Lilly invested heavily in direct to consumer (DTC) advertising. Of the $122 million Defendant Lilly spent on promoting Axiron in 2013, nearly 70% of it ($84 million) funded DTC efforts. Defendant Lilly spent more than double the amount of money on Axiron DTC alone in 2013 than the combined total for all promotional efforts of TRT manufacturers for Testim, Testopel, Fortesta, and Androderm. As stated by Encuity Research, "[m]anufacturers have taken note of how successful DTC advertising has been for driving market share in other lifestyle markets, such as erectile dysfunction, dermatology, and eye care." For its part, having the experience of promoting Cialis for approximately a decade, Defendant Lilly understood the importance of wildly extravagant DTC spending efforts in commercializing Axiron.

422. Defendant Lilly associated with high-profile (and high budget) New York advertising firms to develop a multitude of Axiron commercials, most variations on the same themes of lean and attractive middle-aged men with grey hair applying Axiron and then power boating or sporting (or otherwise exuding masculinity) while their young attractive female partners look upon them lustfully.

423. In addition to the "Vacation" commercial produced by Grey Group and described *supra*, these DTC ads, which are highly suggestive of off-label use and which rarely mention hypogonadism, have won national recognition.

424. For example, Grey New York produced a television ad titled "A New Day" in the Summer of 2013, which won the bronze medal at the 2013 DTC National Advertising Awards. The television ad mentions "hypogonadism" a total of zero (0) times and shows a fit middle-aged man waking up in the morning with a burst of energy, applying Axiron in the bathroom, suiting up and flirting with his attractive wife over breakfast, and then striding confidently into the office as the commercial cuts to Axiron's classical silhouette of a chiseled man applying Axiron to his raised underarms. As observed by Deborah Dick-Rath of Medical Marketing & Media (MM&M), the image is evocative of "a classic Greek statue of a very athletic man who probably never heard of 'low T.'"

425. The "A New Day" commercial was designed to suggest to men that they could use Axiron to treat low energy levels, which is consistent with the off-label messages being developed as part of the Lilly Axiron Peer Selling, Publication, and DTC Enterprises. Defendant Lilly's www.axiron.com website lists "[f]atigue and loss of energy" as one of several "[s]igns and symptoms of low testosterone (Low T)." The FDA has not approved Axiron to treat "[f]atigue and loss of energy," nor has Axiron been proven to be safe or effective at treating "fatigue," which for many men is likely attributable to something other than the rare condition of hypogonadism.

426. Another Axiron television commercial featured our patient and protagonist serving as a lively home plate umpire in a baseball game. As he slaps on his face mask, he extols the listener: "My mantra? Trust your instincts to make the call." The commercial then cuts to our umpire applying Axiron in the bathroom, giving himself a reassuring look in the mirror before leaving the bathroom, and proceeding energetically to call a runner out at home plate. Hypogonadism is again mentioned zero (0) times, and the commercial urges patients to self-

diagnose based on "instincts" and then ask their physicians for treatment. Defendant Lilly manipulated those instincts by suggesting that low testosterone was the root cause of any number of medical conditions and generalized symptoms.

427. Many of these commercials instruct the viewer to "[s]ee our ad in Money Magazine." Money Magazine has a readership of approximately 7.6 million, of which approximately 5 million are men with a median male readership age of 44.5. Consistent with Defendant Lilly's television commercials, which also feature middle-aged men, Defendant Lilly's targeted DTC advertising in Money Magazine and elsewhere was designed specifically to attract middle-aged men with gradually declining, but non-hypogonadal age-appropriate testosterone levels.

428. Overall, the advertisements disseminated by Lilly have suggested that various symptoms often associated with other conditions may instead be caused by low testosterone and encouraged men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" included "decreased sexual desire (libido)," "erectile dysfunction," "fatigue and loss of energy," "depressed mood," "loss of body hair (decreased need to shave)," "decrease in strength," and "osteoporosis (decreased bone density)." All of these are general symptoms that are often a result of aging, weight gain, or lifestyle, rather than conditions associated with hypogonadism.

429. Lilly makes Axiron even more enticing to consumers and physicians by providing an easily downloadable "Savings Card" which can be used for a free 30-day trial and up to $75 in monthly savings on Axiron. The solicitation states: "Your eligible patients with commercial insurance get 1 year of monthly savings with the FIRST MONTH FREE, and pay no more than $25 per month up to a maximum of $75 after the first month free." The website

further encourages physicians to "Download as many as you'd like[.]" For consumers, card activation requires a simple clicking of three buttons: (1) that you are a resident of the United States or Puerto Rico; (2) that you are 18 years old; and (3) that your prescription is not covered by insurance through the government. Once the Savings Card is downloaded and activated, consumers are directed to show the Savings Card and prescription to the consumer's pharmacist. The Savings Card solicitation fails to mention any step regarding consultation with a physician and diagnosis of Hypogonadism.

IX. DEFENDANT ACTAVIS' FRAUDULENT MARKETING OF ANDRODERM

430. Androderm is a prescription TRT medication in the form of a transdermal patch, manufactured by TheraTech Inc. and Actavis Inc. (formerly Watson Pharmaceuticals). Androderm was initially approved for use (2.5 mg and 5.0 mg) by the US FDA on September 29, 1995 to treat adult males who have low or no testosterone due to hypogonadism. On October 11, 2011, the FDA approved 2 mg and 4 mg formulations of Androderm.

431. Androderm is indicated for testosterone replacement therapy in men with a deficiency or absence of endogenous testosterone. This includes cases of primary hypogonadism, which may be caused by cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or alcohol/heavy metal toxicity. It is also prescribed to treat hypogonadotrophic hypogonadism, including in patients with luteinizing hormone or luteinizing hormone-releasing hormone (LHRH) deficiency caused by tumors, injury, or radiation.

432. From 1995 through 1999, Androderm was marketed by SmithKline Beecham under an agreement with TheraTech. In 1999, when Watson purchased TheraTech, it began

marketing Androderm through its own sales force and through a contracted sales force from InVentiv Health.

433. Androderm is applied topically through a patch that adheres to the skin and is applied nightly for 24 hours of medication delivery. Patches come in two different doses, the 2mg patch or the 4mg patch, the 4 mg patch is the recommended dosage. Androderm's most common side effect is listed as skin irritation at the site of the patch. Androderm's product warning label does not include heart attack, stroke or death in its list of health risks.

A. The Androderm Peer Selling Enterprise

434. Defendant Actavis' Peer Selling Enterprise centered on hosting numerous events where doctors trained and/or approved by Defendant Actavis would falsely oversell the efficacy and safety of Androderm and would provide favorable information on the off-label use of Androderm, often under conditions where physicians would be compensated for attending the presentation. Defendant Actavis funded and continues to fund scores of such events from 1999 to present.

435. Indeed, the FDA's DDMAC was concerned about the off-label marketing of Androderm as far back as 1998, when it served a warning letter on SmithKline Beecham Pharmaceuticals ("SKB"), a vendor participant which at that time had acquired marketing and promotion rights to Androderm granted by Defendant Watson. Referencing a "Promotional Dear Doctor Letter" that was "written on SKB letterhead and signed by SKB representatives," the FDA instructed SKB that the letter "is misleading because it suggests that Androderm is safe and effective for treating non-insulin dependent diabetes mellitus (NIDDM) when such has not been demonstrated by adequate and well-controlled clinical trials." Among the statements in the Dear Dr. Letter was the following off-label assertion: "testosterone supplementation … may result in

significant improvements in insulin sensitivity, thereby potentially improving glucose control ….”

436. One example of Defendant Actavis’ Peer Selling Enterprise comes directly from Defendant Actavis’ website. In announcing FDA approval of Androderm 2mg/day and 4mg/day dosing forms, Defendant Actavis’ news release quotes Dr. Jed Kaminetsky: “‘The approval of the new low-dose testosterone patch offers millions of men a reliable and convenient transdermal option for what continues to be an under-diagnosed and undertreated condition,’ said Jed C. Kaminetsky, MD, urologist at University Urology Associates and clinical assistant professor of urology at New York University School of Medicine. ‘The new Androderm® formulation effectively treats symptoms of male hypogonadism, which include decreased sexual desire, fatigue and mood depression. In addition, the patch helps minimize the risk that the testosterone may be transferred from patients to children or women, unlike testosterone gel preparations.’”

437. Assuming Dr. Kaminetsky was involved in the clinical trials supporting FDA approval (a fair assumption since he is quoted in the FDA approval news release), Defendant Actavis did not disclose that Dr. Kaminestsky was contractually obligated to speak out in favor of Androderm. As denoted in the two Watson-sponsored hypogonadism studies on clinicaltrials.gov that supported the Androderm 2mg and 4mg approval, “There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI’s rights to discuss or publish trial results after the trial is completed.” (emphasis from source). Furthermore, Defendant Actavis failed to disclose that Dr. Kaminetsky has been paid hundreds of thousands of dollars by TRT manufacturers, including by Defendant Actavis for “consulting.”

438. Defendant Actavis created and controlled a Peer Selling Enterprise composed of medical marketing firms and several dozen physicians who routinely promoted Androderm to

other physicians in venues all across the country. Defendant Actavis maintained sufficient control over the Androderm Peer Selling Enterprise to select and approve the content of the programs and the physician participants that would deliver the off label message. Physicians who were not receptive to promoting Androderm for the off-label uses were not considered for inclusion in the Androderm Peer Selling Enterprise. The physicians (mostly primary care physicians) who attended these events were deceived into thinking that the events were educational in nature and independent from the control of Defendant Actavis.

439. The Androderm Peer Selling Enterprise employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy of Androderm for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Androderm for both approved indications and for a variety of off-label uses; (c) deliberately concealing negative findings or the absence of positive findings relating to the off-label uses of Androderm; (d) wrongfully and illegally compensating physicians for causing the prescribing of Androderm; (e) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Androderm for both on-label and off-label uses, and then disseminating copies of such studies by the thousands; (f) intentionally misrepresenting and concealing Defendant Actavis' role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Androderm to off-label markets; and (g) intentionally misrepresenting and concealing the financial ties between Defendant Actavis and other participants in the Enterprises.

B. <u>The Androderm Publication Enterprise</u>

440. In order to carry out their Androderm Publication Enterprise, Defendant Actavis and its associates exercised close control to ensure that their off-label Androderm marketing messages were prominently included in seemingly unbiased clinical studies which were in fact the opposite.

441. As part of the Actavis Publication Enterprise, Actavis hired non-physician technical writers and used internal employees to create the necessary articles and then paid the specialists to be the articles' "authors." This practice is referred to as "ghostwriting." In order to monitor the status of publications, and in order to coordinate and execute the ghostwriting plan, marketing firms were necessary. The role played by the firms in assisting each Defendant in creating publications was very similar to the role played by marketing firms in the coordination of peer-to-peer marketing events.

442. Most prominent in Defendant Actavis' Publication Enterprise was the selective publication of data, and through its close control of what study investigators or physician participants could say concerning these trials. Defendant Actavis hand-picked specialists to be study "investigators," but these specialists had little input in the study design and which study results could be released to the public. Defendant Actavis controlled the stream of published information concerning Androderm through its policy of publishing only favorable results of its own internal trials and suppressing results that were unfavorable. For example, the two Watson studies referenced above, bearing clinical trial numbers NCT01104246 ("Dose Titration Investigation of the Pharmacokinetics of Testosterone Transdermal Systems in Hypogonadal Men") and NCT01323140 ("Pharmacokinetics, Metabolism, Efficacy, and Safety Study of Two Testosterone Matrix Transdermal Systems"), have only published selective results. For example, the second trial was both a safety and an efficacy study, with the primary outcome measure

efficacy-related "Percent of Subjects with Testosterone Levels in the Normal Range." No secondary outcome measures have been published or disclosed publicly, where measures such as hematocrit increases might have been taken as part of the study protocol (which has also not been made public). The trial does report study participants having had few adverse events, which is unsurprising given its short duration (30 days), and the fact that there was no data monitoring committee.

443. Making public only favorable results of such studies and at the same time contractually obligating physician participants only to speak favorably of the trial was part of Defendant Actavis' Publication Enterprise. As noted above, the product of this selective publishing was a corpus of data that inaccurately represented safety profiles of the TRT drugs individually and as a class.

444. Feeding into the Peer Selling Enterprise, Defendant Actavis distributed reprints of these publications by the thousands in its physician details. Additionally, Actavis required its physician participants to discuss these study results at peer influence events as part of the publication strategy that intentionally misrepresented each Defendant's role in the creation and sponsorship of the publications. Physicians who reviewed these publications were led to believe that the publications were the independent, unbiased research of the authors of the articles. They were not made aware of the fact that each Defendant had in fact solicited these articles or that they had paid significant sums of money in various forms to the physician authors to induce them to make favorable statements about Defendants' TRT drugs.

445. Defendant Actavis also relied extensively on the Publication Enterprises of the other TRT Defendants, and in particular the AbbVie Defendants' AndroGel Publication Enterprise. For example, under the "Strong Safety Profile" and "Highly Effective" sections of

the Androderm website, Defendant Actavis cites the infamous HIM Study "authored" by Dr. Thomas Mulligan, and which is discussed above. In addition, the Androderm website cites Dandona & Rosenberg, A practical guide to male hypogonadism in the primary care setting, Int. J. Clin. Pract. (2010) 64(6):682-96. The article was funded and sponsored by the AbbVie Defendants and one of its vendor participants as part of its Publication Enterprise. As disclosed in the article: "Writing assistance to the authors was funded by Solvay Pharmaceuticals, Inc. (Solvay) and provided by Robin Smith, PhD, of the Curry Rockefeller Group, on behalf of Solvay. The authors provided guidance and direction at the initiation of the outline and on all drafts, and maintained full control of the intellectual content of this review article."

446. All components of the Androderm Publication Enterprise operated under the exclusive control of Defendant Actavis.

C. The Androderm DTC Enterprise

447. After Androderm was approved by the FDA in 1995, the Actavis Defendants engaged in DTC media campaigns to convince men who were experiencing the typical effects of the aging process that they were suffering from low testosterone, which could be treated with testosterone supplements, including Androderm. The DTC marketing campaign consisted of advertisements, promotional literature placed in healthcare providers' offices and distributed to potential Androderm users, and online media including Defendants' website for Androderm: www.myAndroderm.com.

448. MyAndroderm.com asserts that 4 to 5 million otherwise healthy men experience low testosterone and encourages male visitors to get "a simple blood test" to determine whether they have low T or testosterone. The site also identifies a number of "symptoms" that it

associates with low testosterone which are symptoms that are more commonly associated with aging, weight gain, and lifestyle.

449. The Androderm website also explicitly promotes Androderm off-label. Under the "Highly Effective" tab in bold lettering is the heading, "Effectively Treats Male Hypogonadism." However, the text below contains explicit off-label messaging: "Androderm® 2mg/4mg effectively treats signs and symptoms associated with male hypogonadism, some of which include:

- Erectile dysfunction
- Decreased sexual desire
- Fatigue/loss of energy
- Mood depression

450. Defendant Actavis' DTC Enterprise has sought to convince primary care physicians that low testosterone levels are widely under-diagnosed and that conditions associated with normal aging (such as the ones described above) could be caused by low testosterone levels.

451. As part of its DTC Enterprise, Actavis and its associates promoted Androderm as an easy to apply patch for testosterone replacement therapy. Actavis has contrasted its product's at-home patch with other topical testosterone supplements in that the patch protects against the transfer of testosterone to others and assures proper dosing. *See* Androderm Patches, *available at* http://www.myAndroderm.com/Androderm_patches.aspx#HighlyEffective (last visited October 20, 2014).

452. Actavis' DTC Enterprise encouraged men to discuss testosterone replacement therapy with their doctors and consumers and their physicians relied on promises of safety, effectiveness, and ease of use. Although prescription testosterone replacement therapy has been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

453. Actavis has engaged in aggressive DTC advertising campaigns to grow the market for Androderm. For example, the Androderm website indicates that it is "[f]or men with low testosterone," a condition which the Androderm website claims is largely caused by the aging process. The Androderm website also represents that Androderm is "highly effective" and that its design ensures proper dosing and minimized risks. As stated by Defendant Watson's CEO in a Q3 2011 Earnings Call, "We expanded our sales force in the U.S. by just over 40 reps … to support the launch of the 2 new strands of ANDRODERM."

454. Through DTC marketing campaigns that feature slogans like "Think Beyond the Gel" and "The Patch is Where It's At," Actavis' DTC Enterprise has promoted that the testosterone patch is safer than testosterone gel products, such as AndroGel, which is currently the best selling testosterone replacement therapy.

455. Androderm DTC advertisements have suggested that it is superior to gel products, which are dispensed in a spray pump that could provide inaccurate doses. In addition, testosterone gel side effects may pose a risk for children and women, who may suffer adverse health problems from testosterone if they come into contact with the gel.

456. Unfortunately, a number of recent studies have suggested that men face a serious risk of heart problems from Androderm and all other testosterone products.

457. All components of the Androderm DTC Enterprise operated under the exclusive control and direction of Defendant Actavis.

X. DEFENDANT ENDO'S FRAUDULENT MARKETING OF FORTESTA

458. In a late 2009 deal worth up to approximately $210 million, Defendant Endo acquired a license to commercialize Fortesta in the United States from Prostrakan Group, PLC of Great Britain. David Holveck, president and CEO of Endo, stated that Fortesta "is synergistic

with our recent therapeutic expansion," which includes testosterone injection and testosterone implant products as well.

459. Defendant Endo's Fortesta® Gel ("Fortesta") is a patented two percent (2%) testosterone transdermal gel and is a treatment for men suffering from hypogonadism. Fortesta is delivered transdermally and is applied to the skin in the form of a gel.

460. In August 2009, Endo entered into a License and Supply Agreement (the ProStrakan Agreement) with Strakan International Limited, a subsidiary of ProStrakan Group plc (ProStrakan), for the exclusive right to commercialize Fortesta® Gel in the U.S.

461. The FDA approved Fortesta on December 29, 2010 for the treatment of adult males who have low or no testosterone (a condition called Hypogonadism) in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy. After FDA approval, Fortesta was widely advertised and marketed by Endo as a safe and effective testosterone replacement therapy.

462. Endo launched Fortesta® Gel in the first quarter of 2011. In a March 3, 2011 press release announcing the launch, Endo stated that the "introduction of FORTESTA Gel in the U.S. comes at a time when only about 1.3 million (9 percent) of the estimated 14 million men with Low T are actually receiving treatment."

463. Net sales of Fortesta® Gel were $65.9 million, $30.6 million and $14.9 million for the years ended December 31, 2013, 2012 and 2011, respectively.

A. The Fortesta Peer Selling Enterprise

464. Defendant Endo's Peer Selling Enterprise centered on Endo hosting numerous events where doctors trained and/or approved by Defendant Endo would falsely oversell the

efficacy and safety of Fortesta and would provide favorable information on the off-label use of Fortesta, often under conditions where physicians would be compensated for attending the presentation. Defendant Endo funded and continues to fund scores of such events.

465. In fact, an Encuity Research report detailing the TRT Defendants' promotional efforts in 2013 revealed that Defendant Endo, as a percentage of its total promotional budget, devoted a larger share of that budget toward "Meeting and Events" than did any other TRT manufacturer, including Defendants Lilly and the AbbVie Defendants.

466. Defendant Endo created and controlled a Peer Selling Enterprise composed of medical marketing firms and several dozen physicians who routinely promoted Fortesta to other physicians in venues all across the country. Defendant Endo maintained sufficient control over the Fortesta Peer Selling Enterprise to select and approve the content of the programs and the physician participants that would deliver the off label messages. Physicians who were not receptive to promoting Fortesta for the off-label uses were not considered for inclusion in the Fortesta Peer Selling Enterprise. The physicians (mostly primary care physicians) who attended these events were deceived into thinking that the events were educational in nature and independent from the control of Defendant Endo.

467. The Fortesta Peer Selling Enterprise employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy of Fortesta for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Fortesta for both approved indications and for a variety of off-label uses; (c) deliberately concealing negative findings or the absence of positive findings relating to the off-label uses of Fortesta; (d) wrongfully and illegally compensating physicians for causing the

prescribing of Fortesta; (e) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Fortesta for both on-label and off-label uses, and then disseminating copies of such studies by the thousands; (f) intentionally misrepresenting and concealing Defendant Endo's role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Fortesta to off-label markets; and (g) intentionally misrepresenting and concealing the financial ties between Defendant Endo and other participants in the Fortesta Enterprises.

468. For example, Defendant Endo sponsored a CME-creditable supplement to the Journal of Family Practice with "an educational grant." The title of the CME program centered on so-called "Late-onset male hypogonadism" and the so-called learning objectives included "broadly classify[ing] late-onset male hypogonadism" and the targeted audience included "Family physicians" and primary care physicians "interest[ed] in treating patients with late-onset male hypogonadism." Of course, Fortesta is not approved to treat "late-onset male hypogonadism" and is only approved to treat Primary hypogonadism and Hypogonadotropic hypogonadism. There is no indication for so-called "late-onset male hypogonadism," which is merely a synonym of "andropause" and the natural result of male aging. One of the faculty for this CME publication was Dr. Richard Sadovsky, who disclosed that he serves on Defendant Endo's advisory board, and the medical accuracy reviewer was Dr. Martin Miner, who is on the Auxilium speaker's bureau. Dr. Sadovsky received a $2,500 consulting fee payment on December 8, 2013 according to the CMS Sunshine Act database that recently went online. Defendant Endo's payments to Dr. Sadovsky prior to August 2013 will be examined in discovery.

469. In another example Defendant Endo sponsored an obviously off-label Testosterone Update CME titled "Hypogonadism and Erectile Dysfunction." The faculty for this June 2013 event was Dr. Allen D. Seftel, who disclosed that he was a consultant to AbbVie, Actient, Auxilium, Endo, and Lilly. Dr. Seftel has received tens of thousands of dollars from these pharmaceutical companies, and the CMS Sunshine Act database reveals that Dr. Seftel received a $3,000 payment from Auxilium in November 2013 for "Food and Beverage" purposes. The event, which was organized by Defendant Endo through vendor participants Dannemiller and CogniMed, stated the following for its "Needs Assessment": "Hypogonadism and erectile dysfunction (ED) are under diagnosed and therefore undertreated conditions that can be associated with serious comorbid conditions, including metabolic and cardiovascular disease (CVD). Appropriate screening for comorbidities and treatment by any provider seeing men who are at risk should be encouraged. Mounting evidence indicates that ED and hypogonadism are associated with premature CVD, cardiovascular events, and cardiac death, as well as increased all-cause mortality. Despite compelling evidence, many clinicians are not aware of the connections between ED, hypogonadism, comorbid conditions, and overall health." The event, at Defendant Endo's direction and direct control, sought to convey the Endo marketing message concerning the purported link between ED and hypogonadism to each other and to other co-morbidities to encourage off-label use of Fortesta.

470. In another example, Defendant Endo supported with an "educational grant" an event organized by Fortesta Peer Selling Enterprise vendor participants Postgraduate Institute for Medicine and Miller Communications, LLC, titled "Opioid-Induced Androgen Deficiency: Approaches to Diagnosis and Management." The title of the event explicitly promoted off-label use of Fortesta and other TRT drugs in chronic opioid users. All three (3) faculty – Dr. Michael

J. Brennan (consulting, speaker's bureau), Dr. Andre Guay (speaker's bureau, consulting), and Dr. Abraham Morgentaler (contracted research) – disclosed extensive financial connections to Defendant Endo. The event also falsely suggested that "[t]he opinions expressed in the educational activity are those of the faculty and do not necessarily represent the views of … Endo Pharmaceuticals, Inc." Defendant Endo sought to keep its extensive content control of programs, like the one described, secret, as part of the Peer Selling Enterprise.

471. In addition, Defendant Endo's sales representatives provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the Fortesta, as well as discount and/or rebate coupons to give to patients for the purchase of Fortesta.

472. Defendant Endo's drug sales representatives detailed and marketed Fortesta to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

473. Defendant Endo denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

474. At all times material hereto, Defendant Endo knew and understood the meaning of the term "off-label promotion." Endo knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

475. Defendant Endo has marketed, promoted, and detailed Fortesta for off-label use for the purpose of label expansion, and detailed and promoted the product to physicians in

furtherance of the Peer Selling Enterprise under the rubric that “Low T” was an indication for clinical use of Fortesta.

476. Defendant Endo has promoted and marketed testosterone replacement therapy to physicians as a lifestyle drug that could treat a variety of symptoms caused by the normal aging process in males, including: erectile dysfunction; loss of libido; loss of athleticism; loss of muscle mass; fatigue; and mood swings. Defendant Endo overstated the benefits of testosterone as a treatment for lifestyle changes associated with the aging process despite the fact that the drug was never FDA approved for these uses.

477. Defendant Endo has purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Fortesta. Defendant Endo concealed materially relevant information from potential Fortesta users and their physicians, and minimized user and prescriber concern regarding the safety of Fortesta, including but not limited to its known propensity to drastically increase hematocrit and estradiol levels in users.

478. Defendant has misrepresented that Fortesta is a safe and effective treatment for hypogonadism or "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thromboembolic events.

479. Fortesta causes the hematocrit level to increase, thereby thickening the blood. This effect, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events.

480. Defendant Endo has failed to warn physicians adequately about the risks associated with Fortesta and the monitoring required to ensure the safety of patients using Fortesta.

B. <u>The Fortesta Publication Enterprise</u>

481. In order to carry out their Fortesta Publication Enterprise, the Endo Defendants and their associates exercised close control over publication materials to ensure that their off-label marketing messages were prominently included in seemingly unbiased clinical studies when, in fact, the opposite was true.

482. As part of the Fortesta Publication Enterprise, Endo hired non-physician technical writers and used internal employees to create the necessary articles and then paid the specialists to be the articles' "authors." This practice is referred to as "ghostwriting." In order to monitor the status of publications, and in order to coordinate and execute the ghostwriting plan, marketing firms were necessary. The role played by the firms in assisting each Defendant in creating publications was very similar to the role played by marketing firms in the coordination of peer-to-peer marketing events.

483. One particular example is the article Dr. Adrian S. Dobs, et al., *A Novel Testosterone 2% Gel for the Treatment of Hypogonadal Males,* 33 J. Androl. 601-07 (2012). The article, which is the only study cited by Defendant Endo on its Fortesta healthcare professionals website for both safety and efficacy (http://www.fortestagel.com/hcp/tolerability-and-safety.html *and* http://www.fortestagel.com/hcp/testosterone-gel-efficacy.html), purports to present the results of an independent study involving Fortesta's "novel" 2% testosterone gel for hypogonadal males. In fact, the true purpose of the article was to promote Fortesta on behalf of the Endo Defendants, and is merely exemplary of Defendant Endo's Publication Enterprise. The facts and circumstances surrounding the creation of this study, which are outlined, below, and its purpose were disclosed nowhere on Defendant Endo's Fortesta website.

484. The article discloses that the "study was funded by ProStrakan Pharmaceuticals, Inc." and that "[w]riting and editorial assistance was supported by Endo Pharmaceuticals." These

disclosures are misleading in that Defendant did not just "support" the writing and editorial assistance. Defendant Endo controlled the content of the publication to ensure that the resulting article would support Defendant Endo's intended off-label marketing strategy.

485. As an initial matter, none of the so-called "external authors" disclosed any conflicts of interest to the Defendants, including Dr. Dobs, the lead (and thus cited) author. Two of the authors were ProStrakan employees and one was an Endo employee. Dr. Dobs has received thousands of dollars from TRT pharmaceutical interests over the years, and states on her Johns Hopkins faculty profile that she has "published extensively" on the "risks and benefits of testosterone replacement therapies." According to the CMS Sunshine Act physician payment database, Dr. Dobs, less than a year after publication of this study, received a $3,000 "consulting" payment from Defendant Endo. Payments to Dr. Dobs from Defendant Endo prior to August 2013 will be explored in discovery. However, Dr. Dobs has received tens to hundreds of thousands of dollars of pharmaceutical interests' money over the years, including from Defendant Endo. Most of Dr. Dobs's TRT publications center on the benefits of off-label use.

486. While the Endo Defendants hired doctors to serve as "authors" of the study in order to support the perception that this article was an independent and scientific publication, Endo also took significant steps to ensure that the resulting product presented a message Endo could promote to potential prescribing physicians. After the article's favorable discussion of TRT drugs and of Fortesta as a result of the Endo-funded study, the authors "thank Peter Budka and Catherine Jones (Watermeadow Medical) for their writing and editorial assistance."

487. Watermeadow, an Endo vendor participant, is a medical communications firm that specializes in "Excellence in Medical Communications," publication planning and development, advocacy development and medical education. It has been retained by multiple

pharmaceutical companies to promote their respective products, including Endo Pharmaceuticals for Fortesta.

488. Under the "Scientific Publications" section of its website, Watermeadow states that "[i]nfluential, informative and accurate scientific publication writing underpins all clinical, marketing and sales activities." Under the "Publication planning" section of its website, Watermeadow opens with, "[p]ublication planning is vital to the success of the marketing strategy of any product." Watermeadow also notes that scientific publications are "one of the most influential communication channels for healthcare and scientific audiences." Of course, such channels are influential only when the articles appear to be the result of unbiased research by specialist researchers at teaching universities, such as Dr. Dobs at Johns Hopkins. While most medical writing firms are more discreet about their value to their clients, Watermeadow has understood, and stated on its website that it understood, that Endo intended that and would in fact be using the Dobs et al. article for promotional and sales purposes.

489. Watermeadow Medical's own promotional materials emphasize that its employees will "be working directly with clients" in an effort to "unite scientific and creative flair to maximise the communication of your key messages to the people who matter," and "deliver striking and influential communications that will set you apart from your competition." In an employment brochure describing a day in the life of "Jane," who is a more or less fictional Watermeadow medical writer, "Jane has a sandwich and a chat with colleagues in the communal area at lunchtime, then returns to her desk to go through a draft manuscript which a senior writer has reviewed for her and corrected using tracked changes. Going through them, Jane realizes that the senior writer has filled in some gaps in the discussion and also improved the structure. She makes a mental note of what she needs to do differently next time." Interactions with the study

"authors" as denoted on the final published product appear not to be a part of Jane's normal day as a medical writer.

490. Watermeadow Medical's employment brochure emphasizes the importance of medical writers and medical editors to its efforts. The brochure quotes a medical writer who states, "I choose to work for Watermeadow because it allows me to use my scientific background in a more creative way." However, a scientific background is not required to be employed as a medical writer or editor, and apparently was not in the Dobs *et al*. article created by Watermeadow at Endo's direction. One of the Watermeadow employees who was thanked in the Dobs' article for his "writing and editorial assistance," Peter Budka, holds a B.A. in English Literature and Classics. Defendant Endo and Watermeadow understood that a publication authored by Mr. Budka would not be as influential as a publication by Dr. Dobs, which is why Dr. Dobs was paid for her "authorship" of the study.

491. The Endo Defendants used the efforts of Watermeadow Medical and others to control the misleading messages promoted by the Fortesta Publication Enterprise. These efforts gave the impression that their products were supported by independent science, which allowed them to conceal the serious risks, including cardiovascular health, associated with TRT therapy.

492. Defendant Endo created study protocols consistent with Defendant Endo's intended Fortesta off-label marketing messages, funded these studies to completion, exercised total control over the decision to and the format and substance of the resulting medical journal articles, and paid largely through its vendor participants prominent physicians to lend their names for "authorship" of such articles in exchange for handsome payments. Defendant Endo then masqueraded these predetermined study results, often ghostwritten by Defendant Endo and its vendor participants, as credible science on its websites, through reprints distributed by

Defendant Endo's sales force to physicians, and through physician speakers as part of the Peer Selling Enterprise.

C. The Fortesta DTC Enterprise

493. Defendant Endo and its associates engaged in aggressive, direct-to-consumer and physician marketing and advertising campaigns for Fortesta. Further, Defendant engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "low T."

494. Defendant Endo and its associates published a quiz on the website for Fortesta titled "Could it be Low T?", and encouraged men as young as 35 to take the quiz to find out whether their symptoms are caused by low testosterone levels. According to the "Could it be Low T?" quiz, the symptoms of "Low T" include feeling tired, a loss of body hair, and needing to shave less. See, http://www.gettestedforlowt.com/.

495. In one 2011 DTC ad campaign aimed at physicians, Endo ran ads in Urology Times and other periodicals with the banner "[h]elp replenish his testosterone levels with a low volume gel." This campaign used a gas station pump representation to show how FORTESTA® Gel helps patients with testosterone deficiency "fill back up" and achieve normal testosterone levels. Urology Times has a circulation of over 11,000 urologists in the United States.

496. In a 2012 ad that Endo ran in Urology Times and elsewhere which was aimed at urologists, the company showed two drops of Fortesta Gel to represent two pump actuations on the front of the patient's thigh, and made the claim: "When his pair needs some help, this pair could raise his T."

497. In another DTC advertisement, Endo used the tagline "Pump Up your T" to convince men that "If You're a Man With Low Testosterone (Low T), FORTESTA® Gel Could

Help You." The ad claims that a "small amount of gel applied each day may be all that's need to help raise your T."

498. Endo in 2013 retained healthcare communications company GSW Global from Westerville, Ohio to formulate and design a DTC marketing strategy and marketing plan with respect to Fortesta. In one award-winning direct mail campaign, GSW actually printed a not so subliminal "Fortesta Gel Application Tool" message on boxer shorts to extoll virtues of using Fortesta to treat Low T, which it then mailed to physicians throughout the United States:

After the mailing's January 2013 launch, total prescriptions of Fortesta increased 64% (month-over-month).

499. As a result, diagnoses of Low T have increased exponentially. This has directly related to Fortesta's net sales increasing by 154% in 2013 as compared to 2012.

500. Defendant Endo attributed the sales increase to "improved [MCO] formulary access to this product." *Available at:* http://biz.yahoo.com/e/130806/endp10-q.htm.

501. However, consumers, the Plaintiff and the Class Members were misled as to the drug's safety and efficacy, including for off-label uses, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thromboembolic events.

502. Defendant Endo and its associates successfully marketed Fortesta by undertaking a DTC "disease awareness" marketing campaign which sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low-T."

503. Endo's DTC Enterprise sought to create the image and belief by consumers, their physicians, and TPPs that the use of Fortesta was a safe method of alleviating their symptoms that had few side effects and would not interfere with their daily lives, even though it knew or should have known these assertions to be false, and even though it had no reasonable grounds to believe them to be true.

504. Through its DTC Enterprise, Defendant Endo and its associates purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Fortesta. Defendant Endo deceived potential Fortesta users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

505. Defendant Endo concealed materially relevant information from potential Fortesta users and minimized user and prescriber concern regarding the safety of Fortesta.

506. In particular, in the warnings Defendant Endo and its co-conspirators gave in their DTC Enterprise commercials, online and print advertisements, they fail to mention any potential

cardiac or stroke side effects and falsely represent that Endo adequately tested Fortesta and disclosed results for all likely side effects. Defendant Endo also failed to warn and instruct regarding the importance of adequate monitoring of hematocrit levels. As a result of the DTC Enterprise, men in the United States pervasively seek out prescriptions for Fortesta. If Plaintiff and the Class had known the risks and dangers associated with Fortesta, they would have limited access to Fortesta accordingly.

XI. DEFENDANTS' TARGETING OF TPPS

507. Defendants' fraudulent, deceptive and misleading marketing schemes increased the number of prescriptions of TRT drugs written and filled during the relevant time period. Because each Defendant withheld and misrepresented material information about the safety, efficacy, and usefulness of their TRT drug(s), respectively, for off-label uses, prescribing physicians did not have the knowledge necessary to make informed decisions regarding TRT prescriptions. Plaintiff and the Class Members, unaware of Defendants' scheme, placed TRT drug(s) on preferred branded tiers of their formularies and paid for these prescriptions, relying on many of the same misrepresentations by Defendants. Despite the fact that no alternatives (or more effective and cheaper alternatives) should have been prescribed, Defendants' promotion and marketing of their TRT drug(s) based upon false promises of efficacy and safety for off-label use has been highly successful, resulting in dollars in profits, representing ill-gotten gains to which Defendants were not entitled.

A. TPP Drug Management Programs

508. Pharmacy benefit programs are a common component of the health care benefit offered to insured individuals. TPPs and pharmacy benefit managers ("PBMs") provide and administer pharmacy benefit programs to individuals and process pharmacy claims using a

uniform electronic claim transaction process that is standardized throughout the United States. Plaintiffs and TPPs do not set premium rates taking into account anticipated massive-scale fraudulent off-label promotion by pharmaceutical companies such as Defendants.

509. TPP refers to those entities, other than government agencies, that pay the vast majority of the purchase price of medications on behalf of a group of beneficiaries. TPPs include health insurance plans, as well as Taft-Hartley union health and welfare funds, and self-funded employers with active employee and/or retiree benefit programs.

510. TPPs provide medical and pharmacy benefits to a wide range of organizations nationally, including employers, state and local governments and Medicaid programs.

511. PBMs are organizations that provide services to TPPs for the purpose of providing pharmacy benefits. Rather than processing their own pharmacy claims, most health plans contract with a PBM for this purpose. Likewise, some employers choose to contract directly with a PBM for the management of their pharmacy benefit, rather than acquiring pharmacy benefits through a health plan.

512. There are more than 55 PBMs currently operating in the United States and the range of services provided by these individual companies is substantially similar. All PBMs provide point-of-service claim processing services as described below. In addition, PBMs may contract with retail pharmacies, provide mail order pharmacy services, negotiate rebates with drug manufacturers, develop formularies, and conduct drug utilization review activities.

513. Electronic data interchanges ("EDIs") serve to route the pharmacy claim from the pharmacy, where the claim is generated, to the appropriate payer. This process is completed in the same manner as many forms of electronic claim transmission for credit card and banking procedures through direct managed network connection options, frame relay and Virtual Private

Network ("VPN") technology. Once routed to the TPP or the TPP's PBM, the claim adjudicates against the claim processing system, and is evaluated for a number of edits including the eligibility status of the individual, coverage of the applicable drug, assignment of any prescription edits or messages, determination of the individual's co-pay, co-insurance or deductible, and designation of the approved payment amount.

514. Unlike medical claim transactions which are often processed after the delivery of care, pharmacy claim transactions are completed in nanoseconds, permitting point-of-service ("POS") transactions in the pharmacy. This POS technology can be used to transmit eligibility verification, information about drug interactions, and drug coverage limitations to a pharmacist before the prescription is adjudicated. However, edits that prevent the transmission and acceptance of a claim, such as a prior authorization requirement, can disrupt the patient's access to drug therapy if used indiscriminately. For this reason, most TPP organizations limit claim restrictions to refill timeliness (refill-too-soon), quantity restrictions (30-days' supply) or age restrictions for selected medications. The use of electronic restrictions is largely affected by the standard fields that are populated during the POS claim transaction process.

515. There exist a number of programs or tools available to TPPs and/or their PBMs to manage drug utilization within the insured population. The primary tools available for this purpose are formulary placement after review by the appropriate P&T Committee, cost sharing, claim edits and prior authorization. Several of these are discussed below.

516. The Pharmacy & Therapeutics Committee ("P&T Committee") is an entity established by TPPs and/or PBMs for the purpose of evaluating products that are being considered for formulary placement and developing programs to promote appropriate utilization of pharmaceuticals. The use of P&T Committees is a requirement for health plan accreditation

and is widely used and accepted as the basis for decisions related to a TPP or PBM's formulary. P&T Committees are an established component of health care delivery throughout the TPP sector, including at PBMs, health plans, and government agencies.

517. The typical P&T Committee meets periodically throughout the year, often bi-monthly or once per calendar quarter. When considering drugs in a therapeutic class or new products for consideration on the formulary, P&T members are provided with relevant clinical information about the product, often in the form of a formulary packet or monograph. The information included in this packet is often derived from published medical literature, manufacturer-supplied materials, comments from FDA proceedings (including approval status), and the TPP or PBM's drug utilization experience. The P&T packet is intended to help committee members as they decide which products to include or exclude from formularies and when considering drug management options. Committee members also rely on their own clinical experience.

518. The P&T Committee performs no independent clinical research or laboratory analysis. P&T Committees make recommendations as to which drugs should be included or excluded from formulary. They also provide guidance and approval regarding the use of any tools, such as quantity limits or prior authorization, used in managing the insurance coverage of a specific drug or class of drugs. P&T Committee members do not control prescribing nor do they prevent or mandate the prescribing of any drug for a specific condition.

519. The identity of the P&T Committee membership is highly sought by pharmaceutical companies, including by the TRT Defendants. Because the purpose of drug marketing is to influence prescribing habits, drug makers like Defendants have perceived that direct marketing to P&T Committee members benefit their drug products during the formulary

evaluation process. Pharmaceutical companies, including Defendants, are anxious to know the schedule adopted by the P&T Committee for review of their products. Using this information, they aggressively seek opportunities to promote their products directly to P&T Committee members immediately prior to these review dates. As stated in one internal document, the AbbVie Defendants constantly hoped to cultivate "P&T champions" of their products. Defendant Lilly recently posted a job opening for a Men's Health Sales Rep position in the Washington, DC area on Linkedin. One of the "Responsibilities" for the position included "Identifying and developing influential business relationships with … managed care personnel/organizations when appropriate."

520. P&T Committee members are often invited to participate in "marketing advisory meetings" and other informational sessions sponsored by manufacturers, including Defendants, during which information about products is disseminated. While these sessions can provide valid clinical information about a product, to the extent that information provided by pharmaceutical companies is incorrect or misleading, such information can improperly influence the members of the P&T Committee as they consider formulary initiatives.

521. The formulary is a list of medications that have been selected for the purpose of encouraging high quality and cost-effective prescribing of pharmaceuticals within a patient population. Formularies are segmented by the therapeutic uses of the drugs, often in accordance with established drug classifications systems such as the American Hospital Formulary Service ("AHFS") or the British Formulary Service. Recently, the U.S. Pharmacopeia established a formulary classification system that is used by many Medicare Part D programs. First DataBank® and Medispan® also maintain proprietary drug classification systems used in the claim processing system. In all of these systems, the TRT drugs are classified as androgens, also

called androgenic hormone or testoid, the broad term for any natural or synthetic compound, usually a steroid hormone, that stimulates or controls the development and maintenance of male characteristics in vertebrates by binding to androgen receptors.

522. In addition to the formulary, TPPs may limit coverage of some classes of medication based on the conditions being treated. For example, many TPPs exclude drugs for hair growth, cosmetic products and obesity treatments from standard benefit programs. In contrast, TPPs rarely adopt coverage limitations for drug categories like androgens that are used to treat serious diseases. In fact, universal coverage of these products is mandated under Medicare Part D benefits and by some state regulations. The rationale for drug coverage in these categories is that the diseases are very serious and difficult to treat. TPPs typically try to give prescribers and patients access to all available medications with minimal disruption to care.

523. TPPs can utilize their formularies to promote compliance with national treatment guidelines, to discourage undocumented or non-medical uses of drug therapies, and to educate prescribers regarding the cost-effectiveness of drug treatment options; however, their ability to effectively do so is subject to practical limitations discussed below.

524. The development of the formulary, and of formulary management initiatives, is conducted under the direction of the TPP's P&T Committee or under the P&T Committee of the PBM that is used by the TPP. The use of the P&T Committee for this purpose is meant to assure that the formulary is clinically sound, is sufficiently robust to meet the medical needs of the population being served, and is not unduly burdensome to providers and patients when accessing care.

B. TRT Drugs Have Been Widely Accepted as Preferred Drugs on TPP Formularies

525. Because Defendants' TRT drugs are indicated for the treatment of hypogonadism, a disease that is very serious and sometimes difficult to treat, they have been widely accepted in a preferred position on most TPP formularies. Given the seriousness of these diseases, TPPs and their P&T Committees have been very hesitant to create barriers that would prevent access to effective products for patients suffering from hypogonadism.

526. The decision whether to place a given pharmaceutical product on a drug formulary is first and foremost a clinical decision. The P&T Committee will review the FDA approved clinical indications for the product or products in question and FDA comments associated with the approval of the products. The P&T Committee relies on published studies and other materials that evaluate product efficacy, safety and, when available, directly compare the product to other agents in the appropriate therapeutic category or with comparable clinical uses. Manufacturers like the Defendants often submit a formulary dossier and other materials about their drug products for use by the P&T Committee during the drug review process. The P&T Committee will also review any existing utilization of the product, or of comparable products, by health plan members. The P&T Committee's evaluation is limited to a review of published medical information, such as clinical studies published in peer-reviewed articles and the formulary dossier provided by the manufacturer, and drug utilization data. The P&T Committee does not engage in primary research and cannot detect instances in which information about a drug may have been suppressed by a manufacturer, is unpublished, or is inaccurately represented in the medical literature or other information provided by the manufacturer.

527. TPPs use cost-sharing as a tool when promoting cost-effective utilization of pharmaceuticals. TPPs typically achieve member cost-sharing through three different methods:

(a) deductibles in which the patient pays his or her entire prescription cost until a specific dollar amount has been paid out of pocket; (b) coinsurance, or percentage co-payment, specifies the percentage of the prescription cost that the members pays for each prescription; or (c) co-payments, fixed dollars amounts that members pay for each prescription.

528. Plans can have a single co-payment or co-insurance regardless of the drug type or use a tiered design that allows for different payment amounts for different types of drugs (e.g. generics and brands). Plans may also combine the use of deductibles, co-payments and co-insurance within their benefit programs.

529. Of the various cost-sharing designs used by TPPs, tiered benefits have been widely accepted for many years, and accounted for over 80% of benefit programs offered in 2006. Formularies are often tied to tiered benefits to encourage utilization of lower cost products, particularly for brand and generic medications; however, tiered benefits are not typically used to discourage off-label utilization of medications. By 2002 over 50% of all employers utilized incentive formularies, where the lowest co-pay was charged for generic medications, and higher co-pays were required for second-tier and third-tier medications. The actual co-pay that is charged to patients varies with the benefit plan and has increased over the past several years.

530. In the typical three-tiered formulary, a low co-pay is charged for generic products and a modest co-pay is applied to preferred brand medications, while the highest co-payment levels are reserved for branded medications for which a generic equivalent is available and for non-preferred branded medications. Other benefit plans that are utilized within the insurance industry include four- and five-tier benefits, co-insurance (where the patient typically pays a flat percentage of the cost of the drug), and programs with annual and maximum deductibles. Some

TPP plan benefits assign unique co-pays to very expensive biotechnology products for cost-sharing purposes.

531. Cost-sharing is often aligned with the TPP's formulary in an effort to promote the use of low-cost products and to maximize rebates and discounts on medications, particularly for those drugs which are clinically comparable. For example, proton pump inhibitors ("PPIs"), medications used for the treatment of heartburn, are widely considered to be clinically equivalent. Examples of PPIs include Prilosec, Nexium, Acifex, and Prevacid. While all of these products are very effective, the cost of the products can differ significantly. Prilosec is available in generic form and as an over-the-counter medication. Many P&T Committees have adopted programs to promote generic Prilosec (omeprazole) as a first line agent, with minimal cost-sharing. Because the remaining products are clinically similar, the P&T Committee may consider product cost and rebates offered by manufacturers when selecting a preferred brand product for the formulary. Preferred products are often subject to moderate cost-sharing, while non-preferred agents are subject to higher cost-sharing.

532. TRT drugs have been widely accepted as preferred branded agents and are subject to modest branded cost sharing requirements. From a practical perspective, a TPP would gain little financial advantage in designating TRT drugs as non-preferred agents and assessing a higher co-payment. Because until very recently TRT drug utilization has been relatively low in comparison with many other drugs, the overall financial savings to the pharmacy program were minimal compared to the impact that can be achieved by managing utilization of other drugs. More importantly, a higher co-payment for TRT drugs would result in reduced patient compliance. If this were the case, the cost of managing the disease could far out-weigh any product cost savings attained from a higher co-payment.

533. Prior authorization is a drug management tool that is used when the drug coverage process requires information that cannot be readily obtained through the claim processing system. Such criteria may include diagnosis, laboratory values or other clinical parameters. For example, a health plan may wish to cover growth hormone for deficiency states or Turner's Syndrome, but would wish to exclude the product when it is being prescribed to enhance athletic performance. When a prior authorization is applied, the claim is rejected at the pharmacy and the pharmacist is notified that the prescriber must contact the TPP or the TPP's PBM to obtain approval for coverage, much in the same manner that pre-certification is required for the use of certain health care services.

534. The prior authorization process can be disruptive to care and is expensive to administer. The cost charged by a PBM to administer prior authorizations can exceed $40 per PA request and additional operational costs are incurred by both the TPP and the provider to support the prior authorization process. Equally important, there is frequently great resistance to the prior authorization process by patients and their physicians, as well as from drug manufacturers. Often times, physicians view prior authorization as a threat to their diagnostic and treatment authority and pharmaceutical companies believe prior authorization keeps their products from patients who might benefit from them. Indiscriminate use of prior authorization requirements can result in physician backlash and adversely influence member satisfaction with a health plan. For these reasons, the use of this tool is often limited to drugs that are very expensive and for drugs that have a high potential for inappropriate or non-medical uses. In 2006, a PBMI study found that prior authorization was applied most frequently to experimental

agents, human growth hormones, injectable medications, and infertility therapies, as well as to lifestyle or cosmetic drug uses (erectile dysfunction, weight loss, hair growth).[4]

535. TPPs and/or their PBMs do not have access to the patient's diagnosis as a component of the claim transaction through the POS system. Because it is impossible for TPPs to know the reasons (whether lifestyle-related or for diagnosed hypogonadism) for which TRT drugs were being prescribed when claims are being processed, a prior authorization would be necessary if the TPP's coverage of TRT drugs were limited to FDA-approved diagnoses.

536. At all times material hereto, prior authorization has rarely been used for the management of TRT drugs. Any prior authorization intended to restrict the use of TRT drugs to FDA-approved indications would create a significant barrier to care for those patients with hypogonadism. The efficacy of androgen therapy is highly dependent on patient compliance and consistent drug levels. A prior authorization typically requires 24 to 72 hours for processing. If the patient does not plan for this delay, medication doses may be missed, which may result in an increased potential for delay in initiating the drug therapy.

C. Defendants Deceived TPPs into Placing TRT Drugs in Preferred Formulary Status So that They Could Undertake Their Fraudulent Promotion

537. At all times material hereto, Defendants have undertaken systematic efforts to deceive TPPs into placing their respective TRT drug(s) in the preferred branded status on their formularies in order to treat the very rare condition of hypogonadism. Defendants knew that, relative to the thousands of other drugs on TPP formularies, TRT drugs would likely remain "under the radar" and thus be put on formularies in a preferred branded status – i.e., in a three tier formulary, they would be considered "Tier 2," meaning that members would have the lowest branded co-pay. Defendants knew that, once their TRT drug(s) were on formulary as preferred

[4] *The Prescription Drug Benefit Cost and Plan Design Survey Report*, The Pharmacy Benefit Management Institute, Tempe, AZ, 2007 edition, pg 28.

branded agents, there would be little TPPs could do to control their widespread, illegal off label use. As noted by Acrux in relation to Defendant Lilly, "Tier 2 access to national formulary coverage is critical to the growth and maintenance of market share."

538. Not surprisingly, Defendants have engaged in aggressive contracting to gain favorable formulary status on TPPs formularies. Defendants very closely monitored formulary status, and aggressively contracted with TPPs and/or their PBMs to secure the most favorable formulary status possible. In this way Defendants could ensure that they had access to the lowest tier preferred branded status. Once on formulary, Defendants carefully orchestrated "managed care tactics" to ensure sales representatives "pull through" of prescriptions for their TRT drug(s). For example, a 2005 Solvay Marketing Plan discusses how sales representatives were to emphasize AndroGel's favorable formulary status on every sales call with physicians. One of the "Managed Care Tactics" they were to use to implement their "pull through" strategy was to "target" their systematic Peer Selling Enterprise at TPP P&T Committee members.

539. Although TPPs have a variety of tools that can be used to manage drug costs and promote high quality prescribing and utilization of pharmaceuticals, these tools are not suitable for managing utilization of TRT drugs for off-label indications. Consequently, most TPPs have included TRT drugs on their formularies with few, if any limitations, and at modest branded co-payment levels.

540. Because TRT drugs are indicated for the treatment of hypogonadism, a serious medical condition, the products are widely accepted and are readily available without restrictions on most TPP formularies nationally.

541. TPPs and PBMs are unable to identify off-label uses of TRT drugs from the point-of-service pharmacy claim transaction. The diagnosis for which a drug is prescribed is not

required on a prescription and pharmacies do not have access to diagnostic information at the time a claim is adjudicated. As a result, a diagnosis code is not included as a component of typical claim transactions and is unknown to the TPP and/or its PBM.

542. While the cost of TRT drugs was not insignificant to TPPs, when setting priorities for drug interventions, until very recently, other medication cost-control opportunities were more compelling. With limited resources to implement drug management programs, TPPs prioritize the areas of clinical focus on those therapeutic classes with the highest medical or pharmacy expenditures, on very high cost, often injectable, medications that have a limited range of medical uses, or products with high potential for serious toxicity.

543. At all times material hereto, Defendants were well aware of the limitations faced by TPPs and/or their PBMs in their coverage of TRT drugs.

544. As Defendants learned repeatedly from their advisory board meetings, TPPs and their PBMs cannot readily identify circumstances in which TRT drugs are prescribed for off-label indications. This limitation essentially prevented TPPs from limiting TRT drug coverage to FDA-approved uses.

545. Defendants knew that TPPs and/or their PBMs were unlikely to focus drug management efforts on TRT drugs, preferring instead to use their limited resources to address more pressing concerns.

546. Plaintiff and the Class Members bear the ultimate responsibility for paying for TRT drug prescriptions.

547. In today's health care market, physicians face extreme time constraints in determining which drugs and treatments are best. Physicians, along with P&T Committees, purchasers, PBMs and policy makers rely upon a variety of trusted sources. However,

unbeknownst to the public and to Plaintiff and the Class Members, many of these sources with respect to TRT drugs were directly controlled or heavily influenced by Defendants. All of these sources contained susceptibilities that have been exploited by Defendants.

548. Defendants assaulted patients, physicians, P&T Committees, PBMs, and policy makers with fraudulent TRT messaging from every conceivable angle. DTC advertisements targeting middle-aged men (through placements in Golf Digest or Money Magazine, for example) and the ADAM (or qADAM) screening questionnaire – discussed in detail above – were nebulous enough to succeed in convincing many non-hypogonadal men that they might be suffering from "low T." Defendants hoped that targeted patients would raise the issue of low T with their physicians, leading either to a testosterone test or directly to a TRT prescription.

549. Physicians (mostly primary care physicians) were targeted by their peers, who were often perceived as respected specialists in the fields of urology and endocrinology. Those specialists delivered Defendants' marketing messages (usually presented with slide decks prepared by Defendants) during speaking events, were paid by Defendants for their efforts, and were only maintained on Defendants' roster based on how persuasive they were. Perhaps most damaging, Defendants and/or their associates distorted the medical literature with studies designed and funded by Defendants and conducted by researchers on Defendants' payrolls, and then published scientific articles in some cases "ghostwritten" by Defendants. In cases of "ghostwriting," study "authors" lend their names and reputations to Defendants for a fee.

550. Physicians and P&T Committees/PBMs alike viewed these publications as legitimate science, when in fact they were created by Defendants and served as yet another means to deliver marketing messages masquerading as unbiased science. These very articles and the studies on which they were premised were often cited in drug dossiers provided by

Defendants to P&T Committees/PBMs, including to Plaintiff and the Class Members, which related Defendants' messaging on their TRT drug(s) safety/efficacy profile(s), as well as presented pharmacoeconomic studies proclaiming that TRT drug utilization now could lead to reduced medical treatment expenditures in the future for payors.

551. Formulary decisions of TPPs have a large effect on physicians' prescribing behavior, and such decisions consequently can be the difference between a blockbuster drug and a bust. For example, the AndroGel Defendants, having studied the TPP contracting landscape, noted in 2006 that in "monitoring select [health] plans where AndroGel was the 'exclusive' TRT product, Testim share is significantly lower than national average." Likewise, Acrux noted in a presentation that "Perception of [Axiron] coverage achieved to drive share of Market – being number 2 product on market and being 1 of 2 choices on Lowest Branded Co-Pay (LBC) with key formularies" was a "2014 Axiron US Market Share Driver." In other words, Defendants recognized that a favorable or unfavorable formulary placement could lead to a huge shift in market share.

552. Defendant Auxilium's Form 10-K for 2013 included the following statement emphasizing just how important managed care was to the commercial success of Testim:

> The TRT and ED markets are highly competitive. Our success will depend, in part, on our ability to grow our prescription volume and protect our share of the markets from competitors. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies, and also include compounding pharmacy companies. As competition has increased, access to managed care plans has also become more competitive in the TRT and ED markets. Pricing, rebate and discount strategies required to gain or maintain access or, in some cases, preferential access to certain managed care plans may have a material adverse effect on the revenue we derive from our TRT Products and ED Products. The loss of preferred status or any access at all for

> certain managed care plans may have a material adverse effect on our TRT Products' and/or our ED Products' share of their respective markets.

553. Defendant AbbVie's most recent Form 10-K also emphasizes the importance of managed care customers, and Defendant AbbVie's ability to successfully negotiate terms of inclusion of AbbVie's products on formularies through rebates.

554. In considering how (or even whether) to place a pharmaceutical product on a formulary, P&T Committees and/or PBMs take into account a variety of information. Some important considerations are: the safety/efficacy profile of a product; adverse effects; approved indications; comparison studies; costs and rebates; and medical outcomes and pharmacoeconomic studies.

555. Much of the information relied upon by P&T Committees/PBMs is supplied by or originates from pharmaceutical manufacturers.

556. With respect to AndroGel, the AbbVie Defendants created specific marketing materials and messages targeted at managed care, and dedicated an entire marketing team specifically for that purpose. For example, Defendant Abbott posted a job listing in July 2010 titled "Sr. Product Manager, Managed Health Care – AndroGel" for which the primary responsibilities included: "Establish and communicate strategic positioning for [AndroGel] within the managed marketplace to maximize formulary uptake and sell-through"; "initiate and coordinate pharmacoeconomic outcomes assessment focused on [AndroGel]"; "work with vendors to design promotional materials for use with managed care customer segments." Defendants thus maintain a sales force dedicated to crafting marketing messages that specifically target managed care customers, and those sales materials contain messages specifically addressed to managed care concerns.

557. In the job listing described above, Abbott stressed that helpful prior experience would include making presentations based on clinical data concerning safety/efficacy of AndroGel and pharmacoeconomics to P&T Committees and PBMs: "marketing of healthcare products and/or programs based on clinical outcomes, or economic benefits to high level decision makers is helpful."

558. Indeed, Defendants have presented TRT drug clinical data and pharmacoeconomic studies to Plaintiff and the Class Members and to other P&T Committees and PBMs, which were relied on by Plaintiff and the Class Members in making formulary placement decisions. Defendants stressed in pharmacoeconomic studies and presentations that TRT utilization could lead to healthier lives for aging men, thus reducing overall expenditures.

559. For example, one internal document stated that a means to "Enhance managed care strategy" was to "Deliver strong $ story into details when presenting AndroGel®." This cost-based messaging was specifically created for managed care customers and depended heavily on the AbbVie Defendants' misrepresentations and omissions concerning AndroGel's safety profile.

560. Plaintiff and the Class Members have only recently learned that these presentations were false and misleading with regard to the safety/efficacy profile of the TRT drugs. In addition, such materials were misleading in that they relied on medical literature sponsored and ghostwritten by Defendants.

D. Aggressive TPP Contracting to Ensure Favorable Formulary Placement

561. Recognizing the importance of formulary placements for their TRT drug(s), Defendants made MCO contracting a key priority. As explained in an internal business planning document, the AbbVie Defendants described as a "critical issue" for AndroGel's success to

"[a]ggressively contract with MCO's." As part of this aggressive campaign to win over MCOs, each Defendant submitted drug dossiers for their respective TRT drug(s) discussing clinical studies and safety/efficacy of the drug, and made presentations to P&T Committees/PBMs. Such dossiers and presentations influence the decision-making of P&T Committees/PBMs. In these materials and interactions with P&T Committees and PBMs, Defendants made material misrepresentations and omissions regarding the safety and efficacy profiles of their respective TRT drug(s) with the hope that MCOs would place their product as the preferred TRT product.

562. The AbbVie Defendants submitted so-called "Formulary Support Kits" to P&T Committees and PBMs. The cover letter to one such kit included representations that AndroGel was safe and effective for off-label uses. As stated in the letter, "AndroGel® … resulted in significant increases over time in total body mass, significant improvement in libido and increased degree of penile erection (as determined by patient questionnaire). Additionally, AndroGel® … produced positive effects on mood and fatigue. Bone mineral density in both the hip and spine increased significantly …."

563. In support of such representations, the letter cited the following study: Wang C, Swerdloff RS, Iranmanesh A, et al; and the Testosterone Gel Study Group, *Transdermal testosterone gel improves sexual function, mood, muscle strength, and body composition parameters in hypogonadal men*, 85 J. Clin. Endocrinol Metab. 2839-2853 (2000). The article disclosed zero (0) conflicts of interest, despite the fact that at least several of the "authors" received payments from the AbbVie Defendants and/or their associates. The letter also failed to disclose that the study was funded by Unimed Pharmaceuticals, Inc., Solvay's predecessor and that seven (7) Unimed employees were listed as being part of the "Testosterone Gel Study Group" which was listed among the authors of the article. Finally, the letter asserted to the P&T

Committees and PBMs that "Safety data from clinical studies of AndroGel® demonstrate it to be well tolerated" when Defendants and their associates knew or should have known was false.

564. Defendants closely tracked the formulary status of the TRT drug(s) with various MCO plans. For example, the AbbVie Defendants noted that AndroGel would be at a "major disadvantage" after one formulary placed AndroGel on prior authorization ("PA"), and referred to another MCO's decision to place a step edit requiring failure on patch therapy prior to prescribing AndroGel as a "set-back." In response, the AbbVie Defendants focused on "Enhanc[ing] [the] Managed Care Strategy" in order to drive AndroGel utilization.

565. Had Defendants and/or their associates not misrepresented the safety and efficacy profiles of their TRT drug(s) to Plaintiff and the Class Members, Plaintiff and the Class Members would have had the opportunity to consider implementing formulary management tools like prior authorization, NDC blocks, increased co-pays, and formulary limits.

E. Defendants Used Favorable Formulary Status to "Pull Through" TRT Drug Prescriptions

566. Once a favorable formulary position was achieved, Defendants and/or their associates attempted to "pull through" or "sell through" on the placement by targeting high prescribers within a given health plan. For example, a presentation document for the AbbVie Defendants' Dallas area sales representatives titled "Managed Care Programs and Tactics" included the following tactic: "Maximize formulary status of BCBS/Texas by including status message on all calls with physicians who have high BCBS population." More generally, the same presentation stated the objective to "maximize representative pull-through with MCO's with access to our products."

567. Even if a favorable formulary position was not achieved (for example, if an MCO required prior authorization ("PA") for a TRT drug), Defendants' sales representatives were

trained to be more than eager to fill out the PA forms in order to clear the MCO hurdle for an AndroGel prescription. For example, in one district sales plan, the district manager for AndroGel stated that there was a "lack of P/A forms to insure pull-through" for AndroGel prescriptions. Another challenge was listed as "MCO kick back on several plans." One Auxilium Testopel Area Manager explains on his Linkedin profile that he "Provide[s] problem solving solutions around managed care coverage (Letters of Medical Necessity, Prior Authorizations and Pre-Determinations), Contracting, ICD-9 Billing and Coding updates, Buy and Bill and Specialty Pharmacy procurement services." In other words, if the managed care coverage for Testopel was "problematic" (by, for example, requiring prior authorization), Auxilium's sales force was willing to fill out and submit the PA forms.

568. Defendants and/or their associates also attempted to obscure from MCOs requiring prior authorization that TRT prescriptions were for off-label uses. For example, one AndroGel presentation encouraged as a "managed care tactic" the "utiliz[ation] [of] ICD 9 information to decrease level of resistance from MCO's." In essence, sales representatives encouraged physicians to enter diagnosis codes for hypogonadism so that MCOs would not be alerted to the fact that the AndroGel (or other TRT drug) prescription was off-label. On Defendant Auxilium's Testopel website under the "Reimbursement" tab, Defendant Auxilium offers an easily-downloadable standard form Letter of Medical Necessity. The form letter, which is intended to convince TPP Class Members that Testopel patients suffer from diagnosed hypogonadism, includes addressee fields to be filled out with the address information of Class Member TPPs and reads:

> Dear [Insurance contact name]:
>
> This letter provides clinical justification for [patient's name], a member of your health plan, who has been diagnosed with

> hypogonadism. In order to treat [patient name]'s hypogonadism [patient's name] requires testosterone replacement therapy.
>
> [Patient's name] was first diagnosed with hypogonadism on [date]. The patient is suffering from [loss of energy, mood swings, diminished libido, loss of muscle mass with increased fat accumulation, excessive sleepiness, and possible bone mineral density loss – MD may select or add appropriate symptoms or information here].
> …

569. Notably, Defendant Auxilium does not request that physicians actually test for testosterone deficiency prior to informing TPPs that insureds have been diagnosed with hypogonadism. Instead, Defendant Auxilium suggests that physicians make the diagnosis, and then relate the basis for the diagnosis, as based on symptoms such as "loss of energy" or "excessive sleepiness."

570. Further, as stated by Auxilium Areas Sales Manager Michael Pelish on his Linkedin page (referenced above), Mr. Pelish is more than willing to provide and fill out such letters of medical necessity to be submitted to inquisitive TPPs seeking to confirm a hypogonadism diagnosis prior to reimbursement.

571. Even prior to directly engaging MCOs for contracting, Defendants' and/or their associates' fraudulent promotion campaign targeting physicians with off-label messaging and misrepresentations about the safety and efficacy profile of TRT drugs affected how MCOs would approach formulary placements for the class. As TRT total sales grew from about $18 million in 1997 to over $2 billion today, with AndroGel leading the expansion, Plaintiff and other MCOs felt pressure to negotiate rebates in exchange for formulary placements to keep reimbursement costs manageable. In other words, Defendants' and/or their associates' successful off-label marketing and misrepresentations concerning their TRT drug(s)' safety and efficacy profile(s) served as a primer to allow for successful formulary negotiations with managed care. Acrux

astutely noted this pressure in its push to increase Axiron utilization: "Broadly based formulary coverage has been developed by Lilly since Axiron was introduced to the US market in 2011. Axiron's current ranking as the second highest prescribed product in the gel sector should improve future prospects for national formulary rankings among providers who are targeting a narrower spread of reimbursed products."

572. Defendants and their associates led the way in creating a multi-billion dollar TRT market mostly comprised of off-label sales for "Andropause" or as add-on therapies for existing conditions, which would not have occurred had they not misrepresented the safety and efficacy profiles of their TRT drug(s). Furthermore, since the cardiovascular safety revelations affect the entire class of TRT products, Plaintiff and the Class Members would not have paid for any TRT drug prescription or other pharmaceutical product, as most male aging patients should not have been on any "aging" medication at all, and most patients for other off-label conditions were prescribed TRT drugs as an add-on to existing therapies (e.g., Viagra or Cialis for sexual dysfunction, or any number of products indicated for the treatment of diabetes, such as metformin).

XII. USE OF TRT DRUGS IS TIED TO SERIOUS CARDIOVASCULAR ADVERSE EVENTS

573. Defendants and their associates misrepresented that their TRT drug(s) were safe and effective treatment for both hypogonadism and for the various off-label uses they were promoting as part of its "disease mongering" enterprises, a descriptor used by Dr. Adriane Fugh-Berman of Georgetown University Medical Center to summarize the off-label Peer Selling, Publication, and DTC Enterprises detailed above.

574. In addition to other physiologic adverse health effects caused by TRT drugs, it has recently come to light that TRT drugs cause hematocrit levels to increase, thereby thickening the

blood. This effect, if not monitored and properly controlled, can lead to life-threatening cardiovascular adverse events, including myocardial infarction, stroke, thromboembolic events, and death.

575. Defendants omitted and/or fraudulently misrepresented the safety profiles of TRT drugs in engaging in the aforementioned promotion activities. To wit, Defendants failed to adequately disclose the risks associated with TRT use. As noted in a study published in April 2013, "[n]o randomized placebo-controlled trial has been implemented to assess the effect of testosterone therapy on cardiovascular events[.]" Xu *et al.*, *Testosterone Therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials*, 11 BMC Medicine 108 (April 2013), http://www.biomedcentral.com/1741-7015/11/108 (last checked on September 22, 2014).

576. Defendants and other TRT manufacturers instead focused on studies that were consistent with the marketing messages surrounding their products. A sufficiently powered randomized placebo-controlled study that Defendants knew would have likely confirmed the association of testosterone therapy with increased cardiovascular events would not have been consistent with Defendants marketing messages for TRT, as many targeted patients (including those suffering from erectile dysfunction, obesity, and diabetes) were already susceptible to cardiovascular adverse events.

577. Defendants' respective off-label marketing programs sought to create the image and belief by consumers, physicians, and TPPs (and their P&T Committees) that low testosterone affected a large number of men in the United States and that the use of TRT drugs is safe, even though Defendants knew these assertions to be false, and had no reasonable grounds to believe them to be true.

578. Defendants sought to create a "why not?" attitude with respect to TRT prescription and use. Physicians who were associated with Defendants' respective enterprises, described above, reinforced this blasé attitude toward TRT prescribing. Examples of this from the above allegations include an AndroGel speaker event physician, Dr. Glenn Cunningham, simply exclaiming "YES!!!" in response to an audience member physician's question of whether he should prescribe AndroGel to his osteoporosis patients. Another example is the remark made to the New York Times by Dr. Larry Lipshultz, a frequent Solvay speaker, who stated: "There is no reason to withhold treatment from patients with symptoms and lab reports of low testosterone levels because someone has not done a placebo-controlled study." Both physicians were participants in the Peer Selling Enterprise and were being paid by Defendants to encourage this type of prescribing behavior among their peers. Another example is "e-tractions" explicit efforts to promote Testim off-label to diabetic and erectile dysfunction patients, patient classes already subject to high cardiovascular disease prevalence. Defendant Lilly likewise urged patients to seek Axiron treatment based on "instinct" alone.

579. Of course, these proclamations were misinformed, at best, in light of a number of recent studies demonstrating that testosterone use in men is associated with serious adverse events, including life threatening cardiac events, strokes, and thromboembolic events, including deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous other types of cardiovascular injuries.

580. In late 2009, a Testim study for testosterone therapy in frail and aging men was dramatically halted by the study's drug safety review board after it was discovered that 23 of the 106 patients in the Testim group suffered adverse cardiovascular events, compared to only 5 of the 103 placebo group patients. The study results were published in June 2010 in the New

England Journal of Medicine. *See* Basaria, *et al.*, *Adverse events associated with testosterone administration,* 363 NEJM 109-122 (2010). Defendants, and Auxilium in particular, publicly asserted that the trial's results did not alter its position that TRT drugs were safe and effective. Defendants introduced no cardiovascular warning to their product labeling, and continued to promote TRT drugs as safe and effective for a host of label expanding and off-label conditions.

581. Also in 2010, researchers at the University of California San Francisco (UCSF) studied a group of 700 men aged sixty-five (65) and older. According to the researchers, "Those whose testosterone levels placed them in the top 25 percent of study participants were 2.2 times as likely to experience a heart attack or other event related to heart disease over four years compared to men whose testosterone levels were in the bottom 25 percent."

582. In April 2013, a meta-analysis of twenty-seven (27) randomized, placebo-controlled trials representing 2,994 men was conducted by a group of researchers and published in the Journal of BMC Medicine. Xu *et al.*, *Testosterone Therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials,* 11 BMC 108 (April 2013). The study found that testosterone therapy increased the risk of cardiovascular-related events by approximately 50%. Interestingly, the authors also noted that "[t]he risk of testosterone therapy was particularly marked in trials not funded by the pharmaceutical industry." The FDA observed that the discrepancy could be attributable to "differences in study design or adverse event reporting." Notably, Defendants themselves exercise a great degree of control over study protocols and adverse event reporting guidelines in studies funded by Defendants. In non-industry funded trials, the increased risk of cardiovascular adverse events was upwards of 110%.

583. In November 2013, a study was published in JAMA indicating that testosterone therapy raised the risk of death, heart attack and stroke by about 30%. *See* Vigen, et al., *Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels*, 310 JAMA 1829-1836 (2013). The "Vigen Study" was a retrospective cohort study of VA patients post-angiography with low testosterone levels (< 300ng/dL) from 2005-2011. The researchers found that "the use of testosterone therapy was associated with increased risk of adverse outcomes."

584. In early 2014, Defendant Auxilium stated in its Form 10-K that it "conducted initial clinical trials for a potential high concentration testosterone gel product. However, we do not believe that the clinical results from such studies … warrant further development for this product candidate at this time …." The results of these trials, and many others, are non-public.

585. On January 29, 2014, a large study was released in PLoS ONE, Finkle, et al., *Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men*, 9 PLoS One e85805 (2014). The Finkle study was a retrospective cohort study of 55,593 men from Medicare and health insurance databases. The study investigated the rate of heart attacks among men in the ninety (90) days following a testosterone therapy prescription, and selected as a comparator group men receiving prescriptions for erectile dysfunction drugs, because of similar patient demographics and the fact that erectile dysfunction drugs do not have androgenic effects. The study results indicated that "[a]mong men aged 65 years and older, [the authors] observed a two-fold increase in the risk of [myocardial infarction] in the 90 days after filling an initial [testosterone therapy] prescription …." Similarly, "[a]mong younger men with a history of heart disease, [the authors] observed a two to three-fold increased risk of MI in the 90 days following an initial [testosterone therapy] prescription …." The authors

concluded that, "[t]aken together, the evidence supports an association between testosterone therapy and risk of serious, adverse cardiovascular-related events – including non-fatal myocardial infarction – in men."

586. In June 2014, the FDA announced that it was "requiring manufacturers [of TRT products] to include a general warning in the drug labeling of all approved testosterone products about the risk of blood clots in the veins[,]" including venous thromboembolism and deep vein thrombosis.[5] The TRT drugs labels were updated accordingly. The FDA's evaluation of arterial blood clots and other associated cardiovascular events is ongoing.

587. In some patient populations, TRT drugs may increase the incidence of adverse events and death by over 500%.

588. In addition to the increased risk of cardiovascular adverse events, TRT drugs, and particularly the gel products, have been linked to several severe and life changing medical disorders in both users and those who come into physical contact with users or the unwashed clothes of someone who applied any of the gels. Patients taking TRT drugs may experience enlarged prostates and increased serum prostate-specific antigen levels.

589. Secondary exposure to TRT drugs (and particularly the gels) can cause side effects in others as well. In 2009 the FDA issued a black box warning for the gel products, advising patients of reported virilization in children who were secondarily exposed to the gels. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damage with pregnant women who come into secondary contact with testosterone gel.

590. Defendants' advertising program sought to create the image and belief by consumers and their physicians that the use of TRT drugs was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though

[5] http://www.fda.gov/Drugs/DrugSafety/ucm401746.htm.

Defendants knew these assertions to be false and had no reasonable grounds to believe they were true.

591. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using TRT drugs. Defendants deceived potential TRT drug users by relaying positive information through direct-to-consumer advertising, including press statements and testimonials from retired professional athletes, and by manipulating hypogonadism prevalence numbers while downplaying adverse health effects.

592. Despite the association of testosterone therapy with cardiovascular adverse events, which was known or should have been known to Defendants, Defendants purposefully shied away from conducting an adequately powered randomized placebo-controlled study assessing cardiovascular adverse events as an outcome measure. Even the principal investigator of one such ongoing cardiovascular study sponsored by the AbbVie Defendants, Dr. Peter J. Snyder, conceded that his study was "nowhere near large enough to determine any important risk. Not prostate cancer, not heart disease." Dr. Snyder had argued for a larger study, but, anticipating negative results from an adequately powered study, the AbbVie Defendants are more interested in hedging their bets. If the study's results are positive, the AbbVie Defendants will make the study its champion; if negative, the AbbVie Defendants will emphasize the limitations in the study. As related Dr. Snyder, the most important function of the studies was the "spin" that would inevitably be placed upon the results by the TRT manufacturers. Defendants anticipate that an adequately powered study would produce negative results and would serve merely to alert the public and Plaintiff and the Class Members to the association of testosterone therapy with cardiovascular adverse events.

593. Defendants concealed materially relevant information from potential TRT drug users and from Plaintiff and the Class Members and minimized prescriber concern regarding the safety of TRT drug use.

594. Even after the FDA's required label warning regarding venous thromboembolic adverse events, the TRT Defendants have failed and continue to fail to mention any potential risk of cardiovascular adverse events, stroke, pulmonary embolism or other dangerous side effects related to blood clotting in their commercials, and online and print advertising, and falsely represent that they adequately tested TRT drugs for all likely side effects. Had Defendants adequately disclosed the risks and dangers associated with TRT drugs, consumers and physicians in the United States would not have sought out and prescribed, respectively, anywhere near the volume of TRT drugs that is currently dispensed. In addition, TPPs and other health plans would have made different decisions on how and whether to include TRT drugs on their formularies.

595. These serious adverse health effects are common to the entire class of testosterone replacement therapy.

XIII. DEFENDANTS' CONCEALMENT OF THEIR FRAUDULENT CONDUCT

596. The applicable statutes of limitations regarding the claims of Plaintiff and the Class Members have been tolled by Defendants' fraudulent concealment of their unlawful, conspiratorial deceit, and the deprivation of Plaintiff and Class Members' of the ability to discover the causes of action asserted herein, as alleged in detail throughout this Complaint.

597. As evidenced by the allegations in this Complaint, Defendants have employed and continue to employ practices and techniques of secrecy in order to avoid detection of, and to fraudulently conceal, their deceptive and conspiratorial behavior regarding the safety and efficacy of TRT drugs.

598. Despite taking on the responsibility to reveal this information to the general public, Defendants have kept such information hidden so as to prevent Plaintiff and Class Members from discovering their injuries.

599. As such, Plaintiff and the Class Members were not effectively alerted to the existence and scope of this industry-wide fraud and were not on notice of their potential claims until shortly prior to the filing of this Complaint.

600. Plaintiff and the Class Members could not have acquired such knowledge through the exercise of reasonable diligence. Through their public statements, marketing and advertising, Defendants' self-concealing scheme, which was also designed to prevent TPPs from discovering their injuries, and affirmative conduct to perpetuate their fraud deprived Plaintiff and the Class Members of actual or presumptive knowledge of facts sufficient to put them on notice as to their potential claims.

601. The off-label marketing and publication schemes, as well as the illegal kickback schemes, depended on Defendants' concealment of their involvement, because of the various prohibitions on manufacturers promoting their products off-label and the obvious illegality of bribing physicians in the form of kickbacks. Indeed, Defendants' CME and promotional speaker programs as well as the medical literature and publishing programs, were only successful because Defendants managed to hide the true extent of their control over these activities. Defendants strove to make these CME seminars, medical journal articles, and speaking events appear as legitimate as possible, when in reality the physicians and researchers participating in the schemes were merely the mouthpieces for Defendants' off-label promotions. And, of course, the written materials were in large part less explicit about off-label promotion, even though Defendants trained their sales force to deliver explicit off-label pitches during sales calls.

602. In addition, by polluting the medical literature with studies grossly exaggerating the prevalence of hypogonadism, and by paying prominent physicians to assert that as little as 5-10% of the hypogonadal population were being treated, while concealing their involvement in these studies, the resulting articles, and such statements in reliance on these studies and articles, Defendants sought to create the impression to Plaintiff and the Class Members, to patients, and to physicians that the increased utilization of TRT drugs was for on-label usage that was simply underdiagnosed. It was only recently that that the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee voted 20-1 to limit testosterone prescribing, essentially rejecting the label-expanding efforts of Defendants.

603. Defendants' involvement in these activities was hidden because Defendants largely used intermediaries to conceal their financial connections to physicians. These activities, and others described above, concealed Defendants' off-label promotional activities and were designed such that Plaintiff and the Class Members could not have discovered the alleged scheme or their causes of action earlier in the exercise of reasonable diligence. Much of the scheme – to this day – remains concealed.

604. A False Claims Act whistleblower complaint was filed and unsealed upon the AbbVie Defendants in 2010, and one of the drugs in that lawsuit was AndroGel. However, virtually all of the complaint's exhibits referring to AndroGel remain under seal, and in a December 2013 submission, relator's counsel noted that "document production [in the case] is still in its infancy." In addition, the FCA Plaintiff and the Class Members alleged that much of the AbbVie Defendants' scheme was not reproduced in their complaint. Plaintiff was not aware of the whistleblower case until research for this Complaint was undertaken.

605. Furthermore, due to their illegality, physician kickbacks for prescriptions were concealed or disguised as payments for other purposes for obvious reasons through a number of artifices described above, including sham "honoraria," preceptorships, ALERT testing payments, and other methods.

606. Any applicable statutes of limitation have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein, and of the causes of action available to Plaintiff and Class Members. Plaintiff and the Class Members have been kept in ignorance of vital information essential to the pursuit of these claims without any fault or lack of diligence on their part, and as part of each Defendant's scheme. Plaintiff and the Class Members could not have reasonably discovered the fraudulent nature of Defendants' conduct, and in fact were prevented from discovering the fraudulent nature of Defendants' conduct on account of Defendants's respective schemes to prevent TPPs from discovering that TRT drug use was for ineffective and unsafe off-label uses. Accordingly, Defendants are estopped from relying on any statute of limitations to defeat any of Plaintiff's or the other Class Members' claims.

607. Finally, Defendants concealed the serious adverse side effects of TRT drugs, described above, which were known to Defendants. Plaintiff and the Class Members could not have known nor could they have reasonably discovered TRT drugs' propensity to cause cardiovascular adverse events, which were not generally known until very recently. In fact, the FDA only recently, on January 31, 2014, announced that it was investigating the risk of stroke, heart attack, and death in men taking the entire class of FDA-approved testosterone products.[6]

608. The accrual of all of Plaintiff and the Class Members' claims is tied to these revelations of TRT drugs' poor safety profiles. From an economic damages perspective, the

[6] http://www.fda.gov/Drugs/DrugSafety/ucm383904.htm?utm_source=rss&utm_medium=rss&utm_campaign=fda-evaluating-risk-of-stroke-heart-attack-and-death-with-fda-approved-testosterone-products (last visited June 18, 2014).

existence of and degree to which Plaintiff and the Class Members have been injured is based on the cost difference of alternative medicines that would have been reimbursed absent use of TRT drugs. Until these studies revealed class-wide safety issues for testosterone replacement therapies, the alternative to any single TRT drug would have been other testosterone therapies that are, in many cases, equally as or even more expensive than the product used. With these safety revelations, however, it has become clear that had Defendants not engaged in the off-label promotion, publishing, and DTC Enterprises, *and* had Defendants been forthcoming in disclosing the true safety profiles of TRT drugs as understood by Defendants, for the vast majority of TRT patients, no alternative medicine should have been prescribed at all, thus forming the basis for Plaintiff and the Class Members' injury. Thus, Plaintiff and the Class Members did not discover their injury until the class wide safety issues of testosterone replacement therapies were revealed. These recent discoveries took place within the limitations period.

A. Defendants' Concealment of Serious Side Effects and Negative Safety Profiles

609. Defendants' motive in concealing the serious adverse side effects and negative safety profiles of the TRT drugs, all while controlling and operating the various Enterprises described above, was to obtain additional revenues from the illegal and off-label marketing of their TRT drug(s), which would have had significantly lower sales had it only been sold for its approved indication and if the true safety and efficacy profile of the drug had been disclosed. Due to the conduct described herein, Defendants achieved combined sales near or in excess of $2 billion in both 2012 and 2013.

B. Injury to the Plaintiff and the Class Members: Defendants' Respective Schemes Caused Plaintiff and the Class to Pay for TRT Prescriptions Instead of More Appropriate, Cheaper Alternatives

610. The Enterprises were designed to cause, and did cause, Plaintiff and the Class Members to pay for TRT prescriptions to treat conditions for which the drugs are not FDA-approved and for which there was no reliable scientific evidence that they were effective. On top of this, there was reliable evidence that TRT drugs are not safe when prescribed off-label, and Defendants concealed this information from the public and from TPPs to prevent TPPs from discovering the causes of action asserted herein. Patients, including those whose prescription drug charges were paid by Class Members, and who were prescribed TRT drugs for off-label uses, received no therapeutic benefit and were subject to life threatening side effects. Absent Defendants' conduct, Plaintiff and the Class Members would not have paid for such TRT prescriptions and would not have paid for any substitute product.

611. Defendants' deceptive and misleading marketing scheme increased the number of prescriptions of TRT drugs written and filled during the Class Period. Because Defendants withheld material information about the true safety and efficacy of TRT drugs, the prescribing physicians did not have the knowledge necessary to make informed decisions regarding TRT prescriptions. Plaintiff and the Class Members, unaware of Defendants' scheme, paid for these prescriptions. Although more effective, safer, and less expensive alternatives are available, Defendants' promotion and marketing of TRT safety and effectiveness has been highly successful, resulting in Defendants receiving billions of dollars in profits, representing ill-gotten gains to which Defendants were not entitled.

612. Plaintiff and the Class Members bear the ultimate responsibility of paying for their TRT prescriptions.

613. By directly and falsely promoting TRT drugs as safe and effective for numerous off-label conditions, Defendants influenced PBMs to place TRT drugs on their formularies and at a higher preference on those formularies.

614. Defendants falsely promoted TRT drugs as safe and effective directly to PBMs in order to get TRT drugs placed more favorably on the PBM formularies.

615. Patients, physicians, PBMs, P&T Committee members, and TPPs relied on the Defendants' misrepresentations of TRT safety. Physicians relied on the Defendants' misrepresentations of TRT safety in prescribing the drug for their patients. PBMs and P&T Committees relied on the Defendants' misrepresentations of TRT safety when approving and/or placing TRT drugs on formularies. TPPs relied on the Defendants' misrepresentations of TRT safety in reimbursing and/or paying for prescriptions of TRT drugs for their members.

616. Therefore, Defendants' failure to adequately inform consumers, TPPs and those in the medical community that the use of TRT drugs dangerously increases the risk of cardiovascular adverse events, and their false and misleading promotion of TRT drugs' efficacy over competing less expensive drugs, caused Plaintiff and the Class Members to pay for TRT drugs, which are neither safer nor more effective than other less expensive drugs.

617. But for Defendants' actions, Plaintiff and the Class Members would not have paid for TRT drugs but would instead have paid for safer, equally efficacious drugs or for no drug at all.

C. Defendants' Use of the Mails and Wires to Create and Manage Their Fraudulent Scheme

618. Defendants used, and knowingly caused the use of, mail and interstate wire communications to create, execute, and manage their fraudulent schemes, as well as to further

them. This scheme involved national marketing and sales plans and programs and encompassed physicians and consumers across the country.

619. Defendants' use of, and causing the use of, the mails and wires in furtherance of their schemes to defraud involved thousands of communications and transmissions through the Class period all over the country, including:

- Transmission through mail and wire marketing and advertising materials about the off-label uses of their TRT drug(s) to physicians across the country;
- Communications and transmissions, including financial payments, from Defendants or vendors to participants in the Peer Selling, Publication, and DTC Enterprises, including physicians and medical marketing vendors, discussing and relating to the production and publication of articles and dissemination of materials and speeches misrepresenting the off-label uses and safety and efficacy of their TRT drug(s);
- Communications with Plaintiff and the Class Members, other health insurers, and patients, inducing payments for TRT drugs to be made based on misrepresentations concerning their safety, efficacy, effectiveness, and usefulness; and
- Communications, payments and monetary transfers using the wires concerning the receipt and distribution of the proceeds of Defendants' improper schemes.

620. In addition, Defendants' respective corporate headquarters have communicated, and knowingly caused communications, by United States mail, telephone and facsimile with or by various local district managers, medical liaisons, and pharmaceutical representatives, in furtherance of Defendants' schemes.

XIV. CLASS ACTION ALLEGATIONS

621. Plaintiff brings this suit as a Class action pursuant to Rule 23(b)(2), (b)(3), and (c)(4) of the Federal Rules of Civil Procedure, on behalf of a Class consisting of:

> All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors and any other health benefit provider, in the United States of America and its territories, which paid or incurred costs for the drug AndroGel, Testim, Testopel, Axiron, Fortesta, and/or Androderm for purposes other than resale, since

their respective approval dates. Excluded from the Class are employees of Defendants, including their respective officers or directors, and the Court(s) to which this case is assigned.

622. The proposed Class is sufficiently numerous, as thousands of members of the Class were induced to pay for TRT drugs through Defendants' schemes. The Class Members are so numerous and dispersed throughout the United States that joinder of all members is impracticable. The Class is composed of TPPs, and the disposition of their claims in a Class action will benefit both the parties and the Court. It is estimated that in 2010 alone, at least one million individuals nationwide received prescriptions for TRT drugs that were paid by Plaintiff and the Class Members. Defendants sell millions of doses of TRT drugs in the United States every year, and thus the Class is sufficiently numerous to make joinder impracticable, if not outright impossible. The Class Members can be identified by, *inter alia*, records maintained by Defendants, pharmacies, and PBMs.

623. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class Members are:

a) Whether Defendants misrepresented the safety and efficacy of their respective TRT drug(s);

b) Whether Defendants' acts and omissions violate, *inter alia*, the State Consumer Protection Laws and common law claims;

c) Whether Defendants made material misrepresentations of fact, or omitted to state material facts regarding the several cardiovascular risks associated with their TRT drug(s), which material misrepresentations or omissions operate as a fraud and deceit upon the Class;

d) Whether the Class Members paid more for TRT drugs than for other efficacious drugs that were available at a cheaper price;

e) Whether persons who took TRT drugs are at increased risk of severe and permanent injuries, including cardiovascular adverse events such as myocardial infarction, stroke, and pulmonary embolism;

f) Whether, in marketing and selling TRT drugs, Defendants failed to disclose the dangers and risks to persons ingesting the drugs;

g) Whether Defendants failed to warn adequately of the adverse effects of TRT drugs;

h) Whether Defendants misrepresented in their advertisements, promotional materials and other materials, among other things, the safety, potential side effects and convenience of TRT drugs;

i) Whether Defendants knew or should have known that the ingestion of TRT drugs leads to serious adverse health events; and,

j) Whether Defendants were part of a scheme and/or conspiracy that violated the federal RICO statute.

624. The conduct and patterns of conduct alleged herein, relating to the AbbVie Defendants' sale and marketing of AndroGel, occurred between February 28, 2000, the date of AndroGel's initial approval by the FDA, and before to the extent that the AbbVie Defendants' animal and premarketing studies demonstrated cardiovascular adverse effects and the AbbVie Defendants engaged in pre-approval marketing, up to the present day. The conduct and patterns of conduct occurred and continue to occur well after AbbVie's acquisition of Solvay.

625. The conduct and patterns of conduct alleged herein, relating to Defendant Auxilium's sale and marketing of Testim and Testopel, occurred between approximately 2000 (Testopel) or October 31, 2002 (the date of Testim's initial approval by the FDA), and before to the extent that Defendant Auxilium's animal and premarketing studies demonstrated cardiovascular adverse effects and engaged in pre-approval marketing, up to the present day.

626. The conduct and patterns of conduct alleged herein, relating to Defendant Eli Lilly's sale and marketing of Axiron, occurred between November 23, 2010, the date of Axiron's

initial approval by the FDA, and before to the extent that Defendant Eli Lilly's animal and premarketing studies demonstrated cardiovascular adverse effects and engaged in pre-approval marketing, up to the present day.

627. The conduct and patterns of conduct alleged herein, relating to Defendant Endo's sale and marketing of Fortesta, occurred between December 29, 2010, the date of Fortesta's initial approval by the FDA, and before to the extent that Defendant Endo's animal and premarketing studies demonstrated cardiovascular adverse effects and engaged in pre-approval marketing, up to the present day.

628. The conduct and patterns of conduct alleged herein, relating to Defendant Actavis' sale and marketing of Androderm, occurred between September 29, 1995, the date of Androderm's initial approval by the FDA, and before to the extent that Defendant Actavis' animal and premarketing studies demonstrated cardiovascular adverse effects and engaged in pre-approval marketing, up to the present day.

629. The conduct and patterns of conduct alleged herein, relating to the sale and marketing of TRT drugs, took place throughout the United States, the District of Columbia and Puerto Rico, as well as various other territories and foreign countries. The actual sales and marketing activities described herein were executed principally by Defendants' sales forces and participating physicians and vendors, located all over the country.

630. Plaintiff will fairly and adequately represent and protect the interests of the Class, as required by Rule 23(a)(4). Plaintiff has retained counsel with substantial experience in the prosecution of TRT drug litigation and experience in the prosecution of nationwide class actions. Plaintiff and its counsel are committed to the vigorous prosecution of this action on behalf of the

Class and have the financial resources to do so. Neither Plaintiff nor counsel have any interests in conflict with, or antagonistic to, those of the Class.

631. The Plaintiff seeks compensatory damages against all Defendants, and appropriate equitable, injunctive and declaratory relief and treble damages, under the RICO.

632. The prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications which could establish incompatible standards of conduct for Defendants.

633. Plaintiff and members of the Class have suffered, and will continue to suffer, harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy under Rule 23(b)(3). Absent a class action, because the amount of their individual damages may be relatively small, most members of the Class likely would find the cost and burden of individually litigating their claims to be prohibitive if not impossible, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants, and promotes consistency and efficiency of adjudication. It is also superior because joinder of all members of the Class is impracticable. Class treatment will permit a large number of similarly situated persons and entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would require. The benefits of proceeding by way of class action, including providing injured persons or entities with a method for obtaining redress on claims that they might not be able to pursue individually, substantially outweigh any difficulties that may arise in the management of a class action.

634. Plaintiff does not know of any difficulty that would be encountered in the management of the claims advanced by the Class that would preclude certification.

635. This case presents common issues of fact and law that are appropriate for issue class certification under Rule 23(c)(4); and the management of this action may be facilitated through the certification of additional subclasses under Rule 23(c)(5), if necessary and appropriate.

XV. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The AndroGel Peer Selling Enterprise – Against the AbbVie Defendants)

636. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

637. The AbbVie Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the AndroGel Peer Selling Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

638. The AndroGel Peer Selling Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the AbbVie Defendants, including their employees and agents, (ii) physician and/or physician society participants, including those listed in the foregoing allegations as well as countless other physicians and/or physician societies whose identities are not yet known but will be learned in discovery, (iii) and medical marketing vendors, including those listed in the foregoing allegations as well as numerous other vendors whose identities are not yet known but will be learned in discovery.

639. The AndroGel Peer Selling Enterprise is an ongoing organization that functions as a continuing unit. The AndroGel Peer Selling Enterprise was created and used by the AbbVie

Defendants as a tool to effectuate a pattern of racketeering activity. The AbbVie Defendants "persons" are distinct from the AndroGel Peer Selling Enterprise. The AbbVie Defendants, however, were aware of the essential nature and scope of this Enterprise and intended to participate in and/or conduct it.

640. The AndroGel Peer Selling Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting AndroGel for off-label uses and earning profits therefrom.

641. The AbbVie Defendants have conducted and participated in the affairs of the AndroGel Peer Selling Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the AbbVie Defendants throughout the Class Period number in the thousands, and the AbbVie Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period.

642. The AndroGel Peer Selling Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided AndroGel to thousands of entities and individuals throughout the United States.

643. The AbbVie Defendants exerted control over the AndroGel Peer Selling Enterprise, and the AbbVie Defendants participated in the operation or management of the affairs of the AndroGel Peer Selling Enterprise, through a variety of actions including the following:

- the AbbVie Defendants controlled the content of the messages being delivered by the AndroGel Peer Selling Enterprise at each seminar, event and presentation, and in the publications by the vendor and physician participants, including the misinformation and false statements concerning the safety, efficacy, effectiveness, and usefulness of AndroGel for off-label uses;
- the AbbVie Defendants and their employees and agents controlled the stream of information disseminated by the AndroGel Peer Selling Enterprise concerning AndroGel by exerting control over the communications concerning AndroGel by participant physician and medical marketing vendors;
- the AbbVie Defendants selected and approved the physician participants to deliver the off-label messages for AndroGel at each seminar, speaking event, presentation, or other event where physician participants interacted with other health care providers concerning AndroGel or testosterone replacement therapies;
- the AbbVie Defendants selected the participants of each such event and, more generally, selected the targets of the off-label AndroGel Peer Selling Enterprise;
- the AbbVie Defendants paid the vendor and physician participants for their participation in the AndroGel Peer Selling Enterprise; and
- the AbbVie Defendants placed their own employees and agents in positions of authority and control over the AndroGel Peer Selling Enterprise.

644. As detailed above, the AbbVie Defendants' AndroGel Peer Selling Enterprise consisted of: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which AndroGel was safe and effective so that Plaintiff and the Class Members paid for this drug to treat conditions and/or symptoms for which it was not scientifically proven to be safe,

effective, and useful; (b) presenting seminars and events misrepresenting the off-label uses for which the AbbVie Defendants knew AndroGel was not proven to be scientifically safe, effective, and useful to physician attendees and other healthcare providers; (c) disseminating materials created pursuant to the AndroGel Publication Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which AndroGel was safe and effective and useful; and (d) actively concealing, and causing others to conceal, information about the safety, efficacy, and usefulness of AndroGel to treat conditions for which it had not been approved by the FDA.

645. The AbbVie Defendants' schemes and the above described racketeering activities amounted to common courses of conduct intended to cause Plaintiff and the Class Members to pay for excessive amounts of AndroGel. Within the AndroGel Peer Selling Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. The AbbVie Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff's and the Class Members' property.

646. The pattern of racketeering activities alleged herein and the AndroGel Peer Selling Enterprise are separate and distinct from each other. The AbbVie Defendants engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the AndroGel Peer Selling Enterprise.

647. Plaintiff and the Class Members have been injured in their property by reason of these violations in that they have made millions of dollars in payments for AndroGel that they otherwise would not have made had the AbbVie Defendants not engaged in their pattern of racketeering activities. Plaintiff and the Class Members suffered direct, consequential, and

concrete financial loss flowing from the injury to their property by having overpaid for AndroGel, having received a product or prescription (AndroGel) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the AbbVie Defendants, the Plaintiff and the Class Members would not have suffered their RICO injuries.

648. Plaintiff's and the Class Members' injuries were directly and proximately caused by the AbbVie Defendants' racketeering activity, as described above. Plaintiff's and Class Members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the AbbVie Defendants' scheme; there is no difficulty posed by having to apportion damages among Class Members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the AbbVie Defendants' RICO violations; and there are no others, more directly injured, that could vindicate Plaintiff's and Class Members' claims.

649. By virtue of these violations of 18 U.S.C. § 1962(c), the AbbVie Defendants are jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

SECOND CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Testim and Testopel Peer Selling Enterprise – Against Auxilium)

650. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

651. Defendant Auxilium is a "person" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Testim and Testopel Peer Selling Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

652. The Testim and Testopel Peer Selling Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) Defendant Auxilium, including its employees and agents, (ii) physician and/or physician society participants, including those listed in the foregoing allegations as well as countless other physicians and/or physician societies whose identities are not yet known but will be learned in discovery, (iii) and medical marketing vendors, including those listed in the foregoing allegations as well as countless other vendors whose identities are not yet known but will be learned in discovery.

653. The Testim and Testopel Peer Selling Enterprise is an ongoing organization that functions as a continuing unit. The Testim and Testopel Peer Selling Enterprise was created and used as a tool to effectuate Defendant Auxilium's pattern of racketeering activity. The Defendant Auxilium "persons" are distinct from the Testim and Testopel Peer Selling Enterprise. Defendant Auxilium was aware of the essential nature and scope of this Enterprise and intended to participate in it.

654. The Testim and Testopel Peer Selling Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of groups of "persons" associated together for the common purpose of promoting Testim and Testopel for off-label uses and earning profits therefrom.

655. Defendant Auxilium has conducted and participated in the affairs of the Testim and Testopel Peer Selling Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. §

1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by Defendant Auxilium throughout the Class Period number in the thousands, and the Defendant Auxilium committed, or caused to be committed, at least two of the predicate acts within the requisite ten year period.

656. The Testim and Testopel Peer Selling Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Testim and Testopel to thousands of entities and individuals throughout the United States.

657. Defendant Auxilium exerted control over the Testim and Testopel Peer Selling Enterprise, and participated in the operation or management of its affairs through a variety of actions including the following:

- Defendant Auxilium controlled the content of the messages being delivered by the Testim and Testopel Peer Selling Enterprise at each seminar, event and presentation, and in the publications by the vendor and physician participants, including the misinformation and false statements concerning the safety, efficacy, effectiveness, and usefulness of Testim and Testopel for off-label uses;
- Defendant Auxilium and its employees and agents controlled the stream of information disseminated by the Testim and Testopel Peer Selling Enterprise by exerting control over the communications concerning Testim and Testopel by participant physician and medical marketing vendors;
- Defendant Auxilium selected and approved the physician participants to deliver the off-label messages for Testim and Testopel at each seminar, speaking event, presentation, or other event where physician participants interacted with other health care providers concerning Testim and Testopel or testosterone replacement therapies;

- Defendant Auxilium selected the participants of each such event and, more generally, selected the targets of its off-label Testim and Testopel Peer Selling Enterprise;
- Defendant Auxilium paid the vendor and physician participants for their participation in the Testim and Testopel Peer Selling Enterprise; and
- Defendant Auxilium placed its own employees and agents in positions of authority and control over the Testim and Testopel Peer Selling Enterprise.

658. As detailed above, the Testim and Testopel Peer Selling Enterprise consisted of: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Testim and Testopel were safe and effective so that Plaintiff and the Class Members paid for this drug to treat conditions and/or symptoms for which Testim and Testopel was not scientifically proven to be safe, effective, and useful; (b) presenting seminars and events misrepresenting the off-label uses for which Defendant Auxilium knew Testim and Testopel were not proven to be scientifically safe, effective, and useful to physician attendees and other healthcare providers; (c) disseminating materials created pursuant to the Testim and Testopel Publication Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Testim and Testopel was safe and effective and useful; and (d) actively concealing, and causing others to conceal, information about the safety, efficacy, and usefulness of Testim and Testopel to treat conditions for which they had not been approved by the FDA.

659. Defendant Auxilium's schemes and the above described racketeering activities amounted to common courses of conduct intended to cause Plaintiff and the Class Members to pay for excessive amounts of Testim and Testopel. Within the Testim and Testopel Peer Selling Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar

victims, including Plaintiff and the Class Members. Defendant Auxilium's fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff and the Class Members' property.

660. The pattern of racketeering activities alleged herein and the Testim and Testopel Peer Selling Enterprise are separate and distinct from each other. Defendant Auxilium engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Testim and Testopel Peer Selling Enterprise.

661. Plaintiff and the Class Members have been injured in their property by reason of these violations in that they have made millions of dollars in payments for Testim and Testopel that they otherwise would not have made had Defendants not engaged in their pattern of racketeering activities. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for Testim and Testopel, having received a product or prescription (Testim or Testopel) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Defendant Auxilium, the Plaintiff and the Class Members would not have suffered their RICO injuries.

662. Plaintiff and the Class Members' injuries were directly and proximately caused by Defendant Auxilium's racketeering activity, as described above. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Defendant Auxilium's scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly

injured by the Defendant Auxilium's RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

663. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant Auxilium is jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

THIRD CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Axiron Peer Selling Enterprise – Against the Eli Lilly Defendants)

664. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

665. The Eli Lilly Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Axiron Peer Selling Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

666. The Axiron Peer Selling Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Eli Lilly Defendants, including their employees and agents, (ii) physician and/or physician society participants, including those listed in the foregoing allegations as well as countless other physicians and/or physician societies whose identities are not yet known but will be learned in discovery, (iii) and medical marketing companies, including those listed in the foregoing allegations as well as numerous other companies whose identities are not yet known but will be learned in discovery.

667. The Axiron Peer Selling Enterprise is an ongoing organization that functions as a continuing unit. The Axiron Peer Selling Enterprise was created and used by the Eli Lilly Defendants as a tool to effectuate a pattern of racketeering activity. The Eli Lilly Defendants

"persons" are distinct from the Axiron Peer Selling Enterprise. The Eli Lilly Defendants, however, were aware of the essential nature and scope of this Enterprise and intended to participate in and/or conduct it.

668. The Axiron Peer Selling Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Axiron for off-label uses and earning profits therefrom.

669. The Eli Lilly Defendants have conducted and participated in the affairs of the Axiron Peer Selling Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the Eli Lilly Defendants throughout the Class Period number in the thousands, and the Eli Lilly Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period.

670. The Axiron Peer Selling Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Axiron to thousands of entities and individuals throughout the United States.

671. The Eli Lilly Defendants exerted control over the Axiron Peer Selling Enterprise, and the Eli Lilly Defendants participated in the operation or management of the affairs of the Axiron Peer Selling Enterprise, through a variety of actions including the following:

- the Eli Lilly Defendants controlled the content of the messages being delivered by the Axiron Peer Selling Enterprise at each seminar, event and presentation, and in the publications by the Eli Lilly and physician participants, including the misinformation and

false statements concerning the safety, efficacy, effectiveness, and usefulness of Axiron for off-label uses;

- the Eli Lilly Defendants and their employees and agents controlled the stream of information disseminated by the Axiron Peer Selling Enterprise concerning Axiron by exerting control over the communications concerning Axiron by participant physician and medical marketing;
- the Eli Lilly Defendants selected and approved the physician participants to deliver the off-label messages for Axiron at each seminar, speaking event, presentation, or other event where physician participants interacted with other health care providers concerning Axiron or testosterone replacement therapies;
- the Eli Lilly Defendants selected the participants of each such event and, more generally, selected the targets of the off-label Axiron Peer Selling Enterprise;
- the Eli Lilly Defendants paid the Eli Lilly and physician participants for their participation in the Axiron Peer Selling Enterprise; and
- the Eli Lilly Defendants placed their own employees and agents in positions of authority and control over the Axiron Peer Selling Enterprise.

672. As detailed above, the Eli Lilly Defendants' Axiron Peer Selling Enterprise consisted of: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Axiron was safe and effective so that Plaintiff and the Class Members paid for this drug to treat conditions and/or symptoms for which it was not scientifically proven to be safe, effective, and useful; (b) presenting seminars and events misrepresenting the off-label uses for which the Eli Lilly Defendants knew Axiron was not proven to be scientifically safe, effective, and useful to physician attendees and other healthcare providers; (c) disseminating materials created

pursuant to the Axiron Publication Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Axiron was safe and effective and useful; and (d) actively concealing, and causing others to conceal, information about the safety, efficacy, and usefulness of Axiron to treat conditions for which it had not been approved by the FDA.

673. The Eli Lilly Defendants' schemes and the above described racketeering activities amounted to common courses of conduct intended to cause Plaintiff and the Class Members to pay for excessive amounts of Axiron. Within the Axiron Peer Selling Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. The Eli Lilly Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff and the Class Members' property.

674. The pattern of racketeering activities alleged herein and the Eli Lilly Peer Selling Enterprise are separate and distinct from each other. The Eli Lilly Defendants engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Axiron Peer Selling Enterprise.

675. Plaintiff and the Class Members have been injured in their property by reason of these violations in that they have made millions of dollars in payments for Axiron that they otherwise would not have made had the Eli Lilly Defendants not engaged in their pattern of racketeering activities. Plaintiff and the Class Members suffered direct, consequential, and concrete financial loss flowing from the injury to their property by having overpaid for Axiron, having received a product or prescription (Axiron) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to

be committed by the Eli Lilly Defendants, the Plaintiff and the Class Members would not have suffered their RICO injuries.

676. Plaintiff's and the Class Members' injuries were directly and proximately caused by the Eli Lilly Defendants' racketeering activity, as described above. Plaintiff's and Class Members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Eli Lilly Defendants' scheme; there is no difficulty posed by having to apportion damages among Class Members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the Eli Lilly Defendants' RICO violations; and there are no others, more directly injured, that could vindicate Plaintiff's and Class Members' claims.

677. By virtue of these violations of 18 U.S.C. § 1962(c), the Eli Lilly Defendants are jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

FOURTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Androderm Peer Selling Enterprise – Against the Actavis Defendants)

678. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

679. The Actavis Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Androderm Peer Selling Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

680. The Androderm Peer Selling Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Actavis Defendants, including their employees and agents, (ii) physician and/or physician society participants, including those listed in the foregoing allegations as well as countless other physicians and/or physician societies whose identities are not yet known but will be learned in discovery, (iii) and medical marketing companies, including those listed in the foregoing allegations as well as numerous other companies whose identities are not yet known but will be learned in discovery.

681. The Androderm Peer Selling Enterprise is an ongoing organization that functions as a continuing unit. The Androderm Peer Selling Enterprise was created and used by the Actavis Defendants as a tool to effectuate a pattern of racketeering activity. The Actavis Defendants "persons" are distinct from the Androderm Peer Selling Enterprise. The Actavis Defendants, however, were aware of the essential nature and scope of this Enterprise and intended to participate in and/or conduct it.

682. The Androderm Peer Selling Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Androderm for off-label uses and earning profits therefrom.

683. The Actavis Defendants have conducted and participated in the affairs of the Androderm Peer Selling Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the Actavis Defendants throughout the Class Period number in the

thousands, and the Actavis Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period.

684. The Androderm Peer Selling Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Androderm to thousands of entities and individuals throughout the United States.

685. The Actavis Defendants exerted control over the Androderm Peer Selling Enterprise, and the Actavis Defendants participated in the operation or management of the affairs of the Androderm Peer Selling Enterprise, through a variety of actions including the following:

- the Actavis Defendants controlled the content of the messages being delivered by the Androderm Peer Selling Enterprise at each seminar, event and presentation, and in the publications by Actavis and physician participants, including the misinformation and false statements concerning the safety, efficacy, effectiveness, and usefulness of Androderm for off-label uses;
- the Actavis Defendants and their employees and agents controlled the stream of information disseminated by the Androderm Peer Selling Enterprise concerning Androderm by exerting control over the communications concerning Androderm by participant physicians and medical marketing firms;
- the Actavis Defendants selected and approved the physician participants to deliver the off-label messages for Androderm at each seminar, speaking event, presentation, or other event where physician participants interacted with other health care providers concerning Androderm or testosterone replacement therapies;
- the Actavis Defendants selected the participants of each such event and, more generally, selected the targets of the off-label Androderm Peer Selling Enterprise;

- the Actavis Defendants paid the Actavis and physician participants for their participation in the Androderm Peer Selling Enterprise; and
- the Actavis Defendants placed their own employees and agents in positions of authority and control over the Androderm Peer Selling Enterprise.

686. As detailed above, the Actavis Defendants' Androderm Peer Selling Enterprise consisted of: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Androderm was safe and effective so that Plaintiff and the Class Members paid for this drug to treat conditions and/or symptoms for which it was not scientifically proven to be safe, effective, and useful; (b) presenting seminars and events misrepresenting the off-label uses for Androderm for which the Actavis Defendants knew were not proven to be scientifically safe, effective, and useful to physician attendees and other healthcare providers; (c) disseminating materials created pursuant to the Androderm Publication Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Androderm was safe and effective and useful; and (d) actively concealing, and causing others to conceal, information about the safety, efficacy, and usefulness of Androderm to treat conditions for which it had not been approved by the FDA.

687. The Actavis Defendants' schemes and the above described racketeering activities amounted to common courses of conduct intended to cause Plaintiff and the Class Members to pay for excessive amounts of Androderm. Within the Androderm Peer Selling Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. The Actavis Defendants' fraudulent activities are

part of their ongoing business and constitute a continuing threat to Plaintiff and the Class Members' property.

688. The pattern of racketeering activities alleged herein and the Actavis Peer Selling Enterprise are separate and distinct from each other. The Actavis Defendants engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Androderm Peer Selling Enterprise.

689. Plaintiff and the Class Members have been injured in their property by reason of these violations in that they have made millions of dollars in payments for Androderm that they otherwise would not have made had the Actavis Defendants not engaged in their pattern of racketeering activities. Plaintiff and the Class Members suffered direct, consequential, and concrete financial loss flowing from the injury to their property by having overpaid for Androderm, having received a product or prescription (Androderm) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Actavis Defendants, the Plaintiff and the Class Members would not have suffered their RICO injuries.

690. Plaintiff and the Class Members' injuries were directly and proximately caused by the Actavis Defendants' racketeering activity, as described above. Plaintiff's and Class Members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Actavis Defendants' scheme; there is no difficulty posed by having to apportion damages among Class Members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties

directly injured by the Actavis Defendants' RICO violations; and there are no others, more directly injured, that could vindicate Plaintiff's and Class Members' claims.

691. By virtue of these violations of 18 U.S.C. § 1962(c), the Actavis Defendants are jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

FIFTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Fortesta Peer Selling Enterprise – Against the Endo Defendants)

692. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

693. The Endo Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Fortesta Peer Selling Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

694. The Fortesta Peer Selling Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Endo Defendants, including their employees and agents, (ii) physician and/or physician society participants, including those listed in the foregoing allegations as well as countless other physicians and/or physician societies whose identities are not yet known but will be learned in discovery, (iii) and medical marketing vendors, including those listed in the foregoing allegations as well as numerous other vendors whose identities are not yet known but will be learned in discovery.

695. The Fortesta Peer Selling Enterprise is an ongoing organization that functions as a continuing unit. The Fortesta Peer Selling Enterprise was created and used by the Endo Defendants as a tool to effectuate a pattern of racketeering activity. The Endo Defendants

"persons" are distinct from the Fortesta Peer Selling Enterprise. The Endo Defendants, however, were aware of the essential nature and scope of this Enterprise and intended to participate in and/or conduct it.

696. The Fortesta Peer Selling Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Fortesta for off-label uses and earning profits therefrom.

697. The Endo Defendants have conducted and participated in the affairs of the Fortesta Peer Selling Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the Endo Defendants throughout the Class Period number in the thousands, and the Endo Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period.

698. The Fortesta Peer Selling Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Fortesta to thousands of entities and individuals throughout the United States.

699. The Endo Defendants exerted control over the Fortesta Peer Selling Enterprise, and the Endo Defendants participated in the operation or management of the affairs of the Fortesta Peer Selling Enterprise, through a variety of actions including the following:

- the Endo Defendants controlled the content of the messages being delivered by the Fortesta Peer Selling Enterprise at each seminar, event and presentation, and in the publications by the vendor and physician participants, including the

misinformation and false statements concerning the safety, efficacy, effectiveness, and usefulness of Fortesta for off-label uses;

- the Endo Defendants and their employees and agents controlled the stream of information disseminated by the Fortesta Peer Selling Enterprise concerning Fortesta by exerting control over the communications concerning Fortesta by participant physicians and medical marketing vendors;
- the Endo Defendants selected and approved the physician participants to deliver the off-label messages for Fortesta at each seminar, speaking event, presentation, or other event where physician participants interacted with other health care providers concerning Fortesta or testosterone replacement therapies;
- the Endo Defendants selected the participants of each such event and, more generally, selected the targets of the off-label Fortesta Peer Selling Enterprise;
- the Endo Defendants paid the vendor and physician participants for their participation in the Fortesta Peer Selling Enterprise; and
- the Endo Defendants placed their own employees and agents in positions of authority and control over the Fortesta Peer Selling Enterprise.

700. As detailed above, the Endo Defendants' Fortesta Peer Selling Enterprise consisted of: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Fortesta was safe and effective so that Plaintiff and the Class Members paid for this drug to treat conditions and/or symptoms for which it was not scientifically proven to be safe, effective, and useful; (b) presenting seminars and events misrepresenting the off-label uses for which the Endo Defendants knew Fortesta was not proven to be scientifically safe, effective, and useful to physician attendees and other healthcare providers; (c) disseminating materials created

pursuant to the Fortesta Publication Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Fortesta was safe and effective and useful; and (d) actively concealing, and causing others to conceal, information about the safety, efficacy, and usefulness of Fortesta to treat conditions for which it had not been approved by the FDA.

701. The Endo Defendants' schemes and the above described racketeering activities amounted to common courses of conduct intended to cause Plaintiff and the Class Members to pay for excessive amounts of Fortesta. Within the Fortesta Peer Selling Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. The Endo Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff's and the Class Members' property.

702. The pattern of racketeering activities alleged herein and the Endo Peer Selling Enterprise are separate and distinct from each other. The Endo Defendants engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Fortesta Peer Selling Enterprise.

703. Plaintiff and the Class Members have been injured in their property by reason of these violations in that they have made millions of dollars in payments for Fortesta that they otherwise would not have made had the Endo Defendants not engaged in their pattern of racketeering activities. Plaintiff and the Class Members suffered direct, consequential, and concrete financial loss flowing from the injury to their property by having overpaid for Fortesta, having received a product or prescription (Fortesta) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused

to be committed by the Endo Defendants, the Plaintiff and the Class Members would not have suffered their RICO injuries.

704. Plaintiff's and the Class Members' injuries were directly and proximately caused by the Endo Defendants' racketeering activity, as described above. Plaintiff's and Class Members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Endo Defendants' scheme; there is no difficulty posed by having to apportion damages among Class Members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the Endo Defendants' RICO violations; and there are no others, more directly injured, that could vindicate Plaintiff's and Class Members' claims.

705. By virtue of these violations of 18 U.S.C. § 1962(c), the Endo Defendants are jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

SIXTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The AndroGel Publication Enterprise – Against the AbbVie Defendants)

706. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

707. The AbbVie Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the AndroGel Publication Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

708. The AndroGel Publication Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the AbbVie Defendants, including their employees and agents, (ii) physician and/or researcher participants (including physician societies), including those listed in the foregoing allegations as well as other physicians and/or researchers (including physician societies) whose identities are not yet known but will be learned in discovery, (iii) and medical marketing and/or communications vendors, including those listed in the foregoing allegations as well as other vendors whose identities are not yet known but will be learned in discovery.

709. The AndroGel Publication Enterprise is an ongoing organization that functions as a continuing unit. The AndroGel Publication Enterprise was created and used as a tool to effectuate the AbbVie Defendants' pattern of racketeering activity. The AbbVie Defendants "persons" are distinct from the AndroGel Publication Enterprise. The AbbVie Defendants were aware of the essential nature and scope of this Enterprise and intended to participate in it.

710. The AndroGel Publication Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of groups of "persons" associated together for the common purpose of disseminating publication materials promoting AndroGel for off-label uses not proven to be safe, effective and useful, and earning profits therefrom.

711. The AbbVie Defendants have conducted and participated in the affairs of the AndroGel Publication Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the AbbVie Defendants throughout the Class Period number in the thousands, and

the AbbVie Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten year period.

712. The AndroGel Publication Enterprise engaged in and affected interstate commerce, because, *inter alia*, it operated through medical journals with national subscribership, disseminated reprints of articles to physicians across the nation, and were used as part of the AndroGel Peer Selling Enterprise, which, *inter alia*, marketed, sold, purchased, or provided AndroGel to thousands of entities and individuals throughout the United States.

713. The AbbVie Defendants exerted control over the AndroGel Publication Enterprise, and participated in its operation or management through a variety of actions including the following:

- the AbbVie Defendants controlled the content of the publications, and the marketing messages contained therein, promulgated by the AndroGel Publication Enterprise, including the misinformation and false statements concerning the hypogonadism as well as the safety, efficacy, effectiveness, and usefulness of AndroGel for off-label uses;
- the AbbVie Defendants, and their employees and medical marketing and/or communications vendors, controlled the content of the AndroGel Publication Enterprise publications through ghostwriting, editing, and/or funding or other restrictions for AndroGel studies requiring pre-approval of publications;
- the AbbVie Defendants selected and approved the physician and/or researcher participants to serve as "authors" of publications promoting a more expansive definition of hypogonadism as well as the off-label messages for AndroGel contained therein;
- the AbbVie Defendants targeted specific medical journals for AndroGel or unbranded publications created pursuant to the AndroGel Publication Enterprise;

- the AbbVie Defendants paid the vendor and physician/researcher participants for their participation in the AndroGel Publication Enterprise;
- the AbbVie Defendants placed their own employees and agents in positions of authority and control over the AndroGel Publication Enterprise; and
- the AbbVie Defendants concealed their involvement in the AndroGel Publication Enterprise such that its publications would have a veneer of credibility as independent and unbiased scientific research.

714. As detailed above, the AbbVie Defendants' AndroGel Publication Enterprise consisted of: (a) creating and disseminating publications deliberately misrepresenting, and causing others to misrepresent, the prevalence of hypogonadism and the uses for which AndroGel was safe and effective so that Plaintiff and the Class Members paid for this drug to treat conditions and/or symptoms for which AndroGel was not scientifically proven to be safe, effective, and useful; (b) distributing or causing to be distributed reprints of said publications to physicians misrepresenting the off-label uses for which the AbbVie Defendants knew AndroGel was not proven to be scientifically safe, effective, and useful to physician attendees and other healthcare providers; (c) disseminating materials created pursuant to the AndroGel Publication Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which AndroGel was safe and effective and useful; (d) actively concealing, and causing others to conceal, information about the safety, efficacy, and usefulness of AndroGel to treat conditions for which it had not been approved by the FDA; and (e) actively concealing, and causing others to conceal, the AbbVie Defendants' involvement in the AndroGel Publication Enterprise.

715. The AbbVie Defendants' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiff and the Class Members to pay for excessive amounts of AndroGel. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. The AbbVie Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff's and the Class Members' property.

716. The pattern of racketeering activities alleged herein and the AndroGel Publication Enterprise are separate and distinct from each other. The AbbVie Defendants engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the AndroGel Publication Enterprise.

717. Plaintiff and the Class Members have been injured in their property by reason of these violations in that they have made millions of dollars in payments for AndroGel that they otherwise would not have made had the AbbVie Defendants not engaged in their pattern of racketeering activities. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for AndroGel, having received a product or prescription (AndroGel) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the AbbVie Defendants, the Plaintiff and the Class Members would not have suffered their RICO injuries.

718. Plaintiff and the Class Members' injuries were directly and proximately caused by the AbbVie Defendants' racketeering activity, as described above. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any

independent or intervening factors; their injuries were a foreseeable and natural consequence of the AbbVie Defendants' scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the AbbVie Defendants' RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

719. By virtue of these violations of 18 U.S.C. § 1962(c), the AbbVie Defendants are jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

SEVENTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Testim and Testopel Publication Enterprise – Against Defendant Auxilium)

720. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

721. Defendant Auxilium is a "person" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Testim and Testopel Publication Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

722. The Testim and Testopel Publication Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) Defendant Auxilium, including its employees and agents, (ii) physician and/or researcher participants (including physician societies), including those listed in the foregoing allegations as well as other physicians and/or researchers (including physician societies) whose identities are not yet known but will be learned in discovery, (iii) and medical marketing and/or communications vendors, including those listed

in the foregoing allegations as well as other vendors whose identities are not yet known but will be learned in discovery.

723. The Testim and Testopel Publication Enterprise is an ongoing organization that functions as a continuing unit. The Testim and Testopel Publication Enterprise was created and used as a tool to effectuate Defendant Auxilium's pattern of racketeering activity. The Defendant Auxilium "persons" are distinct from the Testim and Testopel Publication Enterprise.

724. The Testim and Testopel Publication Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of groups of "persons" associated together for the common purpose of disseminating publication materials promoting Testim and Testopel for off-label uses not proven to be safe, effective and useful, and earning profits therefrom.

725. Defendant Auxilium has conducted and participated in the affairs of the Testim and Testopel Publication Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the Defendant Auxilium throughout the Class Period number in the thousands, and the Defendant Auxilium committed, or caused to be committed, at least two of the predicate acts within the requisite ten year period.

726. The Testim and Testopel Publication Enterprise engaged in and affected interstate commerce, because, *inter alia*, it operated through medical journals with national subscribership, disseminated reprints of articles to physicians across the nation, and was used as part of the Testim and Testopel Peer Selling Enterprise, which, *inter alia*, marketed, sold, purchased, or

provided Testim and Testopel to thousands of entities and individuals throughout the United States.

727. Defendant Auxilium exerted control over the Testim and Testopel Publication Enterprise, and participated in its operation or management through a variety of actions including the following:

- Defendant Auxilium controlled the content of the publications, and the marketing messages contained therein, promulgated by the Testim and Testopel Publication Enterprise, including the misinformation and false statements concerning hypogonadism as well as the safety, efficacy, effectiveness, and usefulness of Testim and Testopel for off-label uses;
- Defendant Auxilium, and its employees and medical marketing and/or communications vendors controlled the content of the Testim and Testopel Publication Enterprise publications through ghostwriting, editing, and/or funding or other restrictions for Testim and Testopel studies requiring pre-approval of publications;
- Defendant Auxilium selected and approved the physician and/or researcher participants to serve as "authors" of publications promoting a more expansive definition of hypogonadism as well as the off-label messages for Testim and Testopel contained therein;
- Defendant Auxilium targeted specific medical journals for branded or unbranded publications created pursuant to the Testim and Testopel Publication Enterprise;
- Defendant Auxilium paid the vendor and physician/researcher participants for their participation in the Testim and Testopel Publication Enterprise;

- Defendant Auxilium placed its own employees and agents in positions of authority and control over the Testim and Testopel Publication Enterprise; and
- Defendant Auxilium concealed its involvement in the Testim and Testopel Publication Enterprise so that its publications would have a veneer of credibility as independent and unbiased scientific research.

728. As detailed above, Defendant Auxilium's Testim and Testopel Publication Enterprise consisted of: (a) creating and disseminating publications deliberately misrepresenting, and causing others to misrepresent, the prevalence of hypogonadism and the uses for which Testim and Testopel were safe and effective so that Plaintiff and the Class Members paid for this drug to treat conditions and/or symptoms for which Testim and Testopel were not scientifically proven to be safe, effective, and useful; (b) distributing or causing to be distributed reprints of said publications to physicians misrepresenting the off-label uses for which Defendant Auxilium knew Testim and Testopel were not proven to be scientifically safe, effective, and useful to physician attendees and other healthcare providers; (c) disseminating materials created pursuant to the Testim and Testopel Publication Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Testim and Testopel were safe and effective and useful; (d) actively concealing, and causing others to conceal, information about the safety, efficacy, and usefulness of Testim and Testopel to treat conditions for which they had not been approved by the FDA; and (e) actively concealing, and causing others to conceal, Defendant Auxilium's involvement in the Testim and Testopel Publication Enterprise.

729. Defendant Auxilium's scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiff and the Class Members to

pay for excessive amounts of Testim and Testopel. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. Defendant Auxilium's fraudulent activities are part of its ongoing business and constitute a continuing threat to Plaintiff's and the Class Members' property.

730. The pattern of racketeering activities alleged herein and the Testim and Testopel Publication Enterprise are separate and distinct from each other. Defendant Auxilium engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Testim and Testopel Publication Enterprise.

731. Plaintiff and the Class Members have been injured in their property by reason of these violations in that Plaintiff and the Class Members have made millions of dollars in payments for Testim and Testopel that they otherwise would not have made had Defendant Auxilium not engaged in its pattern of racketeering activities. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for Testim and Testopel, having received a product or prescription (Testim and/or Testopel) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Defendant Auxilium, the Plaintiff and the Class Members would not have suffered their RICO injuries.

732. Plaintiff and the Class Members' injuries were directly and proximately caused by Defendant Auxilium's racketeering activity, as described above. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Defendant

Auxilium's scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the Defendant Auxilium's RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

733. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant Auxilium is jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

EIGHTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Axiron Publication Enterprise – Against Defendant Eli Lilly)

734. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

735. Defendant Eli Lilly is a "person" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Axiron Publication Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

736. The Axiron Publication Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) Defendant Eli Lilly, including its employees and agents, (ii) physician and/or researcher participants (including physician societies), including those listed in the foregoing allegations as well as other physicians and/or researchers (including physician societies) whose identities are not yet known but will be learned in discovery, (iii) and medical marketing and/or communications vendors, including those listed in the foregoing allegations as well as other vendors whose identities are not yet known but will be learned in discovery.

737. The Axiron Publication Enterprise is an ongoing organization that functions as a continuing unit. The Axiron Publication Enterprise was created and used as a tool to effectuate Defendant Eli Lilly's pattern of racketeering activity. The Defendant Eli Lilly "persons" are distinct from the Axiron Publication Enterprise.

738. The Axiron Publication Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of groups of "persons" associated together for the common purpose of disseminating publication materials promoting Axiron for off-label uses not proven to be safe, effective and useful, and earning profits therefrom.

739. Defendant Eli Lilly has conducted and participated in the affairs of the Axiron Publication Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the Defendant Eli Lilly throughout the Class Period number in the thousands, and the Defendant Eli Lilly committed, or caused to be committed, at least two of the predicate acts within the requisite ten year period.

740. The Axiron Publication Enterprise engaged in and affected interstate commerce, because, *inter alia*, it operated through medical journals with national subscribership, disseminated reprints of articles to physicians across the nation, and was used as part of the Axiron Peer Selling Enterprise, which, *inter alia*, marketed, sold, purchased, or provided Axiron to thousands of entities and individuals throughout the United States.

741. Defendant Eli Lilly exerted control over the Axiron Publication Enterprise, and participated in its operation or management through a variety of actions including the following:

- Defendant Eli Lilly controlled the content of the publications, and the marketing messages contained therein, promulgated by the Axiron Publication Enterprise, including the misinformation and false statements concerning the hypogonadism as well as the safety, efficacy, effectiveness, and usefulness of Axiron for off-label uses;
- Defendant Eli Lilly, and its employees and medical marketing and/or communications vendors controlled the content of the Axiron Publication Enterprise publications through ghostwriting, editing, and/or funding or other restrictions for Axiron studies requiring pre-approval of publications;
- Defendant Eli Lilly selected and approved the physician and/or researcher participants to serve as "authors" of publications promoting a more expansive definition of hypogonadism as well as the off-label messages for Axiron contained therein;
- Defendant Eli Lilly targeted specific medical journals for branded or unbranded publications created pursuant to the Axiron Publication Enterprise;
- Defendant Eli Lilly paid the vendors and physician/researcher participants for their participation in the Axiron Publication Enterprise;
- Defendant Eli Lilly placed its own employees and agents in positions of authority and control over the Axiron Publication Enterprise; and
- Defendant Eli Lilly concealed its involvement in the Axiron Publication Enterprise so that its publications would have a veneer of credibility as independent and unbiased scientific research.

742. As detailed above, Defendant Eli Lilly's Axiron Publication Enterprise consisted of: (a) creating and disseminating publications deliberately misrepresenting, and causing others to misrepresent, the prevalence of hypogonadism and the uses for which Axiron was safe and

effective so that Plaintiff and the Class Members paid for this drug to treat conditions and/or symptoms for which Axiron was not scientifically proven to be safe, effective, and useful; (b) distributing or causing to be distributed reprints of said publications to physicians misrepresenting the off-label uses for which Defendant Eli Lilly knew Axiron was not proven to be scientifically safe, effective, and useful to physician attendees and other healthcare providers; (c) disseminating materials created pursuant to the Axiron Publication Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Axiron was safe and effective and useful; (d) actively concealing, and causing others to conceal, information about the safety, efficacy, and usefulness of Axiron to treat conditions for which it had not been approved by the FDA; and (e) actively concealing, and causing others to conceal, Defendant Eli Lilly's involvement in the Axiron Publication Enterprise.

743. Defendant Eli Lilly's scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiff and the Class Members to pay for excessive amounts of Axiron. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. Defendant Eli Lilly's fraudulent activities are part of its ongoing business and constitute a continuing threat to Plaintiff's and the Class Members' property.

744. The pattern of racketeering activities alleged herein and the Axiron Publication Enterprise are separate and distinct from each other. Defendant Eli Lilly engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Axiron Publication Enterprise.

745. Plaintiff and the Class Members have been injured in their property by reason of these violations in that Plaintiff and the Class Members have made millions of dollars in payments for Axiron that they otherwise would not have made had Defendant Eli Lilly not engaged in its pattern of racketeering activities. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for Axiron, having received a product or prescription (Axiron) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Defendant Eli Lilly, the Plaintiff and the Class Members would not have suffered their RICO injuries.

746. Plaintiff's and the Class Members' injuries were directly and proximately caused by Defendant Eli Lilly's racketeering activity, as described above. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Defendant Eli Lilly's scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the Defendant Eli Lilly's RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

747. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant Eli Lilly is jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

NINTH CLAIM FOR RELIEF

Violation of 18 U.S.C. § 1962(c)
(The Androderm Publication Enterprise – Against Defendant Actavis)

748. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

749. Defendant Actavis is a "person" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Androderm Publication Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

750. The Androderm Publication Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) Defendant Actavis, including its employees and agents, (ii) physician and/or researcher participants (including physician societies), including those listed in the foregoing allegations as well as other physicians and/or researchers (including physician societies) whose identities are not yet known but will be learned in discovery, (iii) and medical marketing and/or communications vendors, including those listed in the foregoing allegations as well as other vendors whose identities are not yet known but will be learned in discovery.

751. The Androderm Publication Enterprise is an ongoing organization that functions as a continuing unit. The Androderm Publication Enterprise was created and used as a tool to effectuate Defendant Actavis' pattern of racketeering activity. The Defendant Actavis "persons" are distinct from the Androderm Publication Enterprise.

752. The Androderm Publication Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of groups of "persons" associated together for the common purpose of disseminating publication materials promoting Androderm for off-label uses not proven to be safe, effective and useful, and earning profits therefrom.

753. Defendant Actavis has conducted and participated in the affairs of the Androderm Publication Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the Defendant Actavis throughout the Class Period number in the thousands, and the Defendant Actavis committed, or caused to be committed, at least two of the predicate acts within the requisite ten year period.

754. The Androderm Publication Enterprise engaged in and affected interstate commerce, because, *inter alia*, it operated through medical journals with national subscribership, disseminated reprints of articles to physicians across the nation, and was used as part of the Androderm Peer Selling Enterprise, which, *inter alia*, marketed, sold, purchased, or provided Androderm to thousands of entities and individuals throughout the United States.

755. Defendant Actavis exerted control over the Androderm Publication Enterprise, and participated in its operation or management through a variety of actions including the following:

- Defendant Actavis controlled the content of the publications, and the marketing messages contained therein, promulgated by the Androderm Publication Enterprise, including the misinformation and false statements concerning the hypogonadism as well as the safety, efficacy, effectiveness, and usefulness of Androderm for off-label uses;
- Defendant Actavis, and its employees and medical marketing and/or communications vendors controlled the content of the Androderm Publication Enterprise publications

through ghostwriting, editing, and/or funding or other restrictions for Androderm studies requiring pre-approval of publications;

- Defendant Actavis selected and approved the physician and/or researcher participants to serve as "authors" of publications promoting a more expansive definition of hypogonadism as well as the off-label messages for Androderm contained therein;
- Defendant Actavis targeted specific medical journals for branded or unbranded publications created pursuant to the Androderm Publication Enterprise;
- Defendant Actavis paid the vendors and physician/researcher participants for their participation in the Androderm Publication Enterprise;
- Defendant Actavis placed its own employees and agents in positions of authority and control over the Androderm Publication Enterprise; and
- Defendant Actavis concealed its involvement in the Androderm Publication Enterprise so that its publications would have a veneer of credibility as independent and unbiased scientific research.

756. As detailed above, Defendant Actavis' Androderm Publication Enterprise consisted of: (a) creating and disseminating publications deliberately misrepresenting, and causing others to misrepresent, the prevalence of hypogonadism and the uses for which Androderm was safe and effective so that Plaintiff and the Class Members paid for this drug to treat conditions and/or symptoms for which Androderm was not scientifically proven to be safe, effective, and useful; (b) distributing or causing to be distributed reprints of said publications to physicians misrepresenting the off-label uses for which Defendant Actavis knew Androderm was not proven to be scientifically safe, effective, and useful to physician attendees and other healthcare providers; (c) disseminating materials created pursuant to the Androderm Publication

Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Androderm was safe and effective and useful; (d) actively concealing, and causing others to conceal, information about the safety, efficacy, and usefulness of Androderm to treat conditions for which it had not been approved by the FDA; and (e) actively concealing, and causing others to conceal, Defendant Actavis' involvement in the Androderm Publication Enterprise.

757. Defendant Actavis' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiff and the Class Members to pay for excessive amounts of Androderm. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. Defendant Actavis' fraudulent activities are part of its ongoing business and constitute a continuing threat to Plaintiff's and the Class Members' property.

758. The pattern of racketeering activities alleged herein and the Androderm Publication Enterprise are separate and distinct from each other. Defendant Actavis engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Androderm Publication Enterprise.

759. Plaintiff and the Class Members have been injured in their property by reason of these violations in that Plaintiff and the Class Members have made millions of dollars in payments for Androderm that they otherwise would not have made had Defendant Actavis not engaged in its pattern of racketeering activities. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for Androderm, having received a product or prescription (Androderm) that was worth

less than what they paid for it, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Defendant Actavis, the Plaintiff and the Class Members would not have suffered their RICO injuries.

760. Plaintiff and the Class Members' injuries were directly and proximately caused by Defendant Actavis' racketeering activity, as described above. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Defendant Actavis' scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the Defendant Actavis' RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

761. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant Actavis is jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

TENTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Fortesta Publication Enterprise – Against Defendant Endo)

762. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

763. Defendant Endo is a "person" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Fortesta Publication Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

764. The Fortesta Publication Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) Defendant Endo, including its employees and agents, (ii) physician and/or researcher participants (including physician societies), including those listed in the foregoing allegations as well as other physicians and/or researchers (including physician societies) whose identities are not yet known but will be learned in discovery, (iii) and medical marketing and/or communications vendors, including those listed in the foregoing allegations as well as other vendors whose identities are not yet known but will be learned in discovery.

765. The Fortesta Publication Enterprise is an ongoing organization that functions as a continuing unit. The Fortesta Publication Enterprise was created and used as a tool to effectuate Defendant Endo's pattern of racketeering activity. The Defendant Endo "persons" are distinct from the Fortesta Publication Enterprise.

766. The Fortesta Publication Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of groups of "persons" associated together for the common purpose of disseminating publication materials promoting Fortesta for off-label uses not proven to be safe, effective and useful, and earning profits therefrom.

767. Defendant Endo has conducted and participated in the affairs of the Fortesta Publication Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the Defendant Endo throughout the Class Period number in the thousands, and the Defendant Endo committed, or caused to be committed, at least two of the predicate acts within the requisite ten year period.

768. The Fortesta Publication Enterprise engaged in and affected interstate commerce, because, *inter alia*, it operated through medical journals with national subscribership, disseminated reprints of articles to physicians across the nation, and were used as part of the Fortesta Peer Selling Enterprise, which, *inter alia*, marketed, sold, purchased, or provided Fortesta to thousands of entities and individuals throughout the United States.

769. Defendant Endo exerted control over the Fortesta Publication Enterprise, and participated in its operation or management through a variety of actions including the following:

- Defendant Endo controlled the content of the publications, and the marketing messages contained therein, promulgated by the Fortesta Publication Enterprise, including the misinformation and false statements concerning hypogonadism as well as the safety, efficacy, effectiveness, and usefulness of Fortesta for off-label uses;
- Defendant Endo, and its employees and medical marketing and/or communications vendors controlled the content of the Fortesta Publication Enterprise publications through ghostwriting, editing, and/or funding or other restrictions for Fortesta studies requiring pre-approval of publications;
- Defendant Endo selected and approved the physician and/or researcher participants to serve as "authors" of publications promoting a more expansive definition of hypogonadism as well as the off-label messages for Fortesta contained therein;
- Defendant Endo targeted specific medical journals for branded or unbranded publications created pursuant to the Fortesta Publication Enterprise;
- Defendant Endo paid the vendor and physician/researcher participants for their participation in the Fortesta Publication Enterprise;

- Defendant Endo placed its own employees and agents in positions of authority and control over the Fortesta Publication Enterprise; and
- Defendant Endo concealed its involvement in the Fortesta Publication Enterprise so that its publications would have a veneer of credibility as independent and unbiased scientific research.

770. As detailed above, Defendant Endo's Fortesta Publication Enterprise consisted of: (a) creating and disseminating publications deliberately misrepresenting, and causing others to misrepresent, the prevalence of hypogonadism and the uses for which Fortesta was safe and effective so that Plaintiff and the Class Members paid for this drug to treat conditions and/or symptoms for which Fortesta was not scientifically proven to be safe, effective, and useful; (b) distributing or causing to be distributed reprints of said publications to physicians misrepresenting the off-label uses for which Defendant Endo knew Fortesta was not proven to be scientifically safe, effective, and useful to physician attendees and other healthcare providers; (c) disseminating materials created pursuant to the Fortesta Publication Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Fortesta was safe and effective and useful; (d) actively concealing, and causing others to conceal, information about the safety, efficacy, and usefulness of Fortesta to treat conditions for which it had not been approved by the FDA; and (e) actively concealing, and causing others to conceal, Defendant Endo's involvement in the Fortesta Publication Enterprise.

771. Defendant Endo's scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiff and the Class Members to pay for excessive amounts of Fortesta. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar

results affecting similar victims, including Plaintiff and the Class Members. Defendant Endo's fraudulent activities are part of its ongoing business and constitute a continuing threat to Plaintiff and the Class Members' property.

772. The pattern of racketeering activities alleged herein and the Fortesta Publication Enterprise are separate and distinct from each other. Defendant Endo engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Fortesta Publication Enterprise.

773. Plaintiff and the Class Members have been injured in their property by reason of these violations in that Plaintiff and the Class Members have made millions of dollars in payments for Fortesta that they otherwise would not have made had Defendant Endo not engaged in its pattern of racketeering activities. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for Fortesta, having received a product or prescription (Fortesta) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Defendant Endo, the Plaintiff and the Class Members would not have suffered their RICO injuries.

774. Plaintiff's and the Class Members' injuries were directly and proximately caused by Defendant Endo's racketeering activity, as described above. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Defendant Endo's scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly

injured by the Defendant Endo's RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

775. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant Endo is jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

ELEVENTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The AndroGel DTC Enterprise – Against the AbbVie Defendants)

776. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

777. The AbbVie Defendants participated in the conduct of the affairs of the AndroGel DTC Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

778. The AndroGel DTC Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of the AbbVie Defendants, including their employees and agents, the marketing firms and publication firms that Defendants associated with to market AndroGel directly to patients, and the web designers who created websites to promote unfounded uses directly to consumers.

779. The AbbVie Defendants are RICO "persons" distinct from the AndroGel DTC Enterprise.

780. The AbbVie Defendants used the AndroGel DTC Enterprise to carry out their scheme to obtain money by means of false and fraudulent pretenses, representations, and omissions.

781. The AndroGel DTC Enterprise is an ongoing organization that functions as a continuing unit.

782. The AbbVie Defendants and the other members of the AndroGel DTC Enterprise created and maintained systematic links for the common purpose of gaining revenue from marketing AndroGel for on- and off-label uses. Each of the members of the AndroGel DTC Enterprise received substantial revenue from marketing AndroGel. Such revenue was exponentially greater than it would have been if AndroGel had been marketed appropriately.

783. The AndroGel DTC Enterprise has a hub and spoke organizational, decision-making structure, with the AbbVie Defendants serving as the hub.

784. All members of the AndroGel DTC Enterprise were aware of the AbbVie Defendants' control over its activities. Furthermore, each member of the AndroGel DTC Enterprise benefited from the existence of the other members.

785. The AndroGel DTC Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, distributed, sold, and provided AndroGel to thousands of individuals and entities throughout the United States.

786. The AbbVie Defendants have exerted control over the AndroGel DTC Enterprise and have managed its affairs through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), and § 1952 (use of interstate facilities to conduct unlawful activity).

787. The AbbVie Defendants' use of, or causation of the use of, the mails and wires to perpetrate their fraud through the AndroGel DTC Enterprise involved hundreds of communications including, but not limited to: (a) marketing materials and advertisements aimed at patients that misrepresented that AndroGel was safe and effective for off-label uses for which

the drug was not legitimately proven safe and effective; (b) communications with patients including Plaintiff's and Class Members' participants and their dependents, as well as TPPs including Plaintiff and the Class Members, inducing payments for AndroGel to be made based on misrepresentations concerning the risks and benefits of AndroGel; and (c) receiving the proceeds of their improper scheme. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the AbbVie Defendants throughout the Class Period consisted of at least two of the predicate acts within a ten year period.

788. In addition, the AbbVie Defendants' corporate headquarters have communicated by United States mail, telephone, and facsimile with various local district managers, medical liaisons, and sales representatives in order to use the AndroGel DTC Enterprise to carry out their schemes to obtain money by means of false and fraudulent pretenses, representations, and omissions.

789. Further, the AbbVie Defendants have traveled in interstate or foreign commerce or used the mail and facilities in interstate or foreign commerce, with the intent to distribute the proceeds of the unlawful activity described above or otherwise promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on of the unlawful activity described above.

790. The AbbVie Defendants' racketeering activities related to the AndroGel DTC Enterprise amounted to a common course of conduct intended to deceive and harm Plaintiff and the Class Members. Each racketeering activity was related, had similar purposes, involved the same or similar members and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. The AbbVie Defendants' racketeering

activities are part of their ongoing businesses and constitute a continuing threat to the property of Plaintiff and the Class Members.

791. The AbbVie Defendants' repeated use of the AndroGel DTC Enterprise to implement and carry out the fraudulent schemes constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. §§ 1961(5) and 1962(c). Through that pattern of racketeering activity, the AbbVie Defendants conducted and participated in the conduct of the affairs of the AndroGel DTC Enterprise.

792. Plaintiff and the Class Members have been directly injured in their business and property by reason of the AbbVie Defendants' violations of 18 U.S.C. § 1962(c) in that the pattern of racketeering activity that they used to conduct the affairs of the AndroGel DTC Enterprise directly and proximately caused Plaintiff and the Class Members to spend excessive, ascertainable sums of money for the purchase, payment, or reimbursement of AndroGel prescriptions that would not have been purchased, paid, or reimbursed if the AbbVie Defendants had not conducted or participated in the conduct of the affairs of the AndroGel DTC Enterprise through a pattern of racketeering activity. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for AndroGel, having received a product or prescription (AndroGel) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses.

793. Plaintiff and the Class Members have also been directly injured in their business and property by reason of the AbbVie Defendants' violations of 18 U.S.C. § 1962(c) in that the pattern of racketeering activity that the AbbVie Defendants used to conduct the affairs of the AndroGel DTC Enterprise directly and proximately caused Plaintiff and the Class Members to spend excessive, ascertainable sums of money for the purchase or reimbursement of AndroGel

sold at a falsely inflated price that would have been significantly lower if the AbbVie Defendants had not conducted or participated in the conduct of the affairs of the AndroGel DTC Enterprise through a pattern of racketeering activity.

794. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the AbbVie Defendants' scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the AbbVie Defendants' RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

795. By virtue of these violations of 18 U.S.C. § 1962(c), the AbbVie Defendants are jointly and severally liable to Plaintiff and the Class Members for three times the damages they have sustained, plus the cost of this suit, punitive damages, including reasonable attorney's fees.

TWELFTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Testim and Testopel DTC Enterprise – Against Defendant Auxilium)

796. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

797. Defendant Auxilium participated in the conduct of the affairs of the Testim and Testopel DTC Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

798. The Testim and Testopel DTC Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendant Auxilium, including its employees and

agents, the marketing firms and publication firms that Defendant Auxilium associated with to market Testim and Testopel directly to patients, and the web designers who created websites to promote unfounded uses directly to consumers.

799. Defendant Auxilium is a RICO "person" distinct from the Testim and Testopel DTC Enterprise.

800. Defendant Auxilium used the Testim and Testopel DTC Enterprise to carry out its scheme to obtain money by means of false and fraudulent pretenses, representations, and omissions.

801. The Testim and Testopel DTC Enterprise is an ongoing organization that functions as a continuing unit.

802. Defendant Auxilium and the other members of the Testim and Testopel DTC Enterprise created and maintained systematic links for the common purpose of gaining revenue from marketing Testim and Testopel for on- and off-label uses. Each of the members of the Testim and Testopel DTC Enterprise received substantial revenue from marketing Testim and Testopel. Such revenue was exponentially greater than it would have been if Testim and Testopel were marketed appropriately.

803. The Testim and Testopel DTC Enterprise has a hub and spoke organizational, decision-making structure, with Defendant Auxilium serving as the hub.

804. All members of the Testim and Testopel DTC Enterprise were aware of Defendant Auxilium's control over the activities of the Testim and Testopel DTC Enterprise. Furthermore, each member of the Testim and Testopel DTC Enterprise benefited from the existence of the other members.

805. The Testim and Testopel DTC Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, distributed, sold, and provided Testim and Testopel to thousands of individuals and entities throughout the United States.

806. Defendant Auxilium has exerted control over the Testim and Testopel DTC Enterprise and has managed its affairs through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), and § 1952 (use of interstate facilities to conduct unlawful activity).

807. Defendant Auxilium's use of, or causation of the use of, the mails and wires to perpetrate its fraud through the Testim and Testopel DTC Enterprise involved hundreds of communications including, but not limited to: (a) marketing materials and advertisements aimed at patients that misrepresented that Testim and Testopel were safe and effective for off-label uses for which the drug was not legitimately proven safe and effective; (b) communications with patients including Plaintiff's and Class Members' participants and their dependents, inducing payments for Testim and Testopel to be made based on misrepresentations concerning its risks and benefits; and (c) receiving the proceeds of its improper scheme. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the Defendant Auxilium throughout the Class Period consisted of at least two of the predicate acts within a ten year period.

808. In addition, Defendant Auxilium's corporate headquarters have communicated by United States mail, telephone, and facsimile with various local district managers, medical liaisons, and sales representatives in order to use the Testim and Testopel DTC Enterprise to carry out its schemes to obtain money by means of false and fraudulent pretenses, representations, and omissions.

809. Further, Defendant Auxilium has traveled in interstate or foreign commerce or used the mail and facilities in interstate or foreign commerce, with the intent to distribute the proceeds of the unlawful activity described above or otherwise promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on of the unlawful activity described above.

810. Defendant Auxilium's racketeering activities related to the Testim and Testopel DTC Enterprise amounted to a common course of conduct intended to deceive and harm Plaintiff and the Class Members. Each racketeering activity was related, had similar purposes, involved the same or similar members and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. Defendant Auxilium's racketeering activities are part of its ongoing businesses and constitute a continuing threat to the property of Plaintiff and the Class Members.

811. Defendant Auxilium's repeated use of the Testim and Testopel DTC Enterprise to implement and carry out the fraudulent schemes constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. §§ 1961(5) and 1962(c). Through that pattern of racketeering activity, Defendant Auxilium conducted and participated in the conduct of the affairs of the Testim and Testopel DTC Enterprise.

812. Plaintiff and the Class Members have been directly injured in their business and property by reason of Defendant Auxilium's violations of 18 U.S.C. § 1962(c) in that the pattern of racketeering activity that Defendant Auxilium used to conduct the affairs of the Testim and Testopel DTC Enterprise directly and proximately caused them to spend excessive, ascertainable sums of money for the purchase, payment, or reimbursement of Testim and Testopel prescriptions that would not have been purchased, paid, or reimbursed if Defendant Auxilium

had not conducted or participated in the conduct of the affairs of the Testim and Testopel DTC Enterprise through a pattern of racketeering activity. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for Testim and Testopel, having received a product or prescription (Testim and/or Testopel) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses.

813. Plaintiff and the Class Members have also been directly injured in their business and property by reason of Defendant Auxilium's violations of 18 U.S.C. § 1962(c) in that the pattern of racketeering activity that it used to conduct the affairs of the Testim and Testopel DTC Enterprise directly and proximately caused Plaintiff and the Class Members to spend excessive, ascertainable sums of money for the purchase or reimbursement of Testim and Testopel sold at a falsely inflated price that would have been significantly lower if Defendant Auxilium had not conducted or participated in the conduct of the affairs of the Testim and Testopel DTC Enterprise through a pattern of racketeering activity.

814. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Defendant Auxilium's scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the Defendant Auxilium's RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

815. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant Auxilium is jointly and severally liable to Plaintiff and the Class Members for three times the damages they have sustained, plus the cost of this suit, punitive damages, including reasonable attorney's fees.

THIRTEENTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Axiron DTC Enterprise – Against Defendant Eli Lilly)

816. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

817. Defendant Eli Lilly participated in the conduct of the affairs of the Axiron DTC Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

818. The Axiron DTC Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendant Eli Lilly, including its employees and agents, the marketing firms and publication firms that Defendant Eli Lilly associated with to market Axiron directly to patients, and the web designers who created websites to promote unfounded uses directly to consumers.

819. Defendant Eli Lilly is a RICO "person" distinct from the Axiron DTC Enterprise.

820. Defendant Eli Lilly used the Axiron DTC Enterprise to carry out its scheme to obtain money by means of false and fraudulent pretenses, representations, and omissions.

821. The Axiron DTC Enterprise is an ongoing organization that functions as a continuing unit.

822. Defendant Eli Lilly and the other members of the Axiron DTC Enterprise created and maintained systematic links for the common purpose of gaining revenue from marketing Axiron for on- and off-label uses. Each of the members of the Axiron DTC Enterprise received

substantial revenue from marketing Axiron. Such revenue was exponentially greater than it would have been if Axiron were marketed appropriately.

823. The Axiron DTC Enterprise has a hub and spoke organizational, decision-making structure, with Defendant Eli Lilly serving as the hub.

824. All members of the Axiron DTC Enterprise were aware of Defendant Eli Lilly's control over the activities of the Axiron DTC Enterprise. Furthermore, each member of the Axiron DTC Enterprise benefited from the existence of the other members.

825. The Axiron DTC Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, distributed, sold, and provided Axiron to thousands of individuals and entities throughout the United States.

826. Defendant Eli Lilly has exerted control over the Axiron DTC Enterprise and has managed its affairs through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), and § 1952 (use of interstate facilities to conduct unlawful activity).

827. Defendant Eli Lilly's use of, or causation of the use of, the mails and wires to perpetrate its fraud through the Axiron DTC Enterprise involved hundreds of communications including, but not limited to: (a) marketing materials and advertisements aimed at patients that misrepresented that Axiron was safe and effective for off-label uses for which the drug was not legitimately proven safe and effective; (b) communications with patients including Plaintiff's and Class Members' participants and their dependents, inducing payments for Axiron to be made based on misrepresentations concerning its risks and benefits; and (c) receiving the proceeds of its improper scheme. The unlawful predicate acts of racketeering activity committed, or caused

to be committed, by the Defendant Eli Lilly throughout the Class Period consisted of at least two of the predicate acts within a ten year period.

828. In addition, Defendant Eli Lilly's corporate headquarters have communicated by United States mail, telephone, and facsimile with various local district managers, medical liaisons, and sales representatives in order to use the Axiron DTC Enterprise to carry out its schemes to obtain money by means of false and fraudulent pretenses, representations, and omissions.

829. Further, Defendant Eli Lilly has traveled in interstate or foreign commerce or used the mail and facilities in interstate or foreign commerce, with the intent to distribute the proceeds of the unlawful activity described above or otherwise promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on of the unlawful activity described above.

830. Defendant Eli Lilly's racketeering activities related to the Axiron DTC Enterprise amounted to a common course of conduct intended to deceive and harm Plaintiff and the Class Members. Each racketeering activity was related, had similar purposes, involved the same or similar members and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. Defendant Eli Lilly's racketeering activities are part of its ongoing businesses and constitute a continuing threat to the property of Plaintiff and the Class Members.

831. Defendant Eli Lilly's repeated use of the Axiron DTC Enterprise to implement and carry out the fraudulent schemes constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. §§ 1961(5) and 1962(c). Through that pattern of racketeering activity,

Defendant Eli Lilly conducted and participated in the conduct of the affairs of the Axiron DTC Enterprise.

832. Plaintiff and the Class Members have been directly injured in their business and property by reason of Defendant Eli Lilly's violations of 18 U.S.C. § 1962(c) in that the pattern of racketeering activity that Defendant Eli Lilly used to conduct the affairs of the Axiron DTC Enterprise directly and proximately caused them to spend excessive, ascertainable sums of money for the purchase, payment, or reimbursement of Axiron prescriptions that would not have been purchased, paid, or reimbursed if Defendant Eli Lilly had not conducted or participated in the conduct of the affairs of the Axiron DTC Enterprise through a pattern of racketeering activity. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for Axiron, having received a product or prescription (Axiron) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses.

833. Plaintiff and the Class Members have also been directly injured in their business and property by reason of Defendant Eli Lilly's violations of 18 U.S.C. § 1962(c) in that the pattern of racketeering activity that it used to conduct the affairs of the Axiron DTC Enterprise directly and proximately caused Plaintiff and the Class Members to spend excessive, ascertainable sums of money for the purchase or reimbursement of Axiron sold at a falsely inflated price that would have been significantly lower if Defendant Eli Lilly had not conducted or participated in the conduct of the affairs of the Axiron DTC Enterprise through a pattern of racketeering activity.

834. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a

foreseeable and natural consequence of the Defendant Eli Lilly's scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the Defendant Eli Lilly's RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

835. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant Eli Lilly is jointly and severally liable to Plaintiff and the Class Members for three times the damages they have sustained, punitive damages, plus the cost of this suit, including reasonable attorney's fees.

FOURTEENTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Androderm DTC Enterprise – Against Defendant Actavis)

836. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

837. Defendant Actavis participated in the conduct of the affairs of the Androderm DTC Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

838. The Androderm DTC Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendant Actavis, including its employees and agents, the marketing firms and publication firms that Defendant Actavis associated with to market Androderm directly to patients, and the web designers who created websites to promote unfounded uses directly to consumers.

839. Defendant Actavis is a RICO "person" distinct from the Androderm DTC Enterprise.

840. Defendant Actavis used the Androderm DTC Enterprise to carry out its scheme to obtain money by means of false and fraudulent pretenses, representations, and omissions.

841. The Androderm DTC Enterprise is an ongoing organization that functions as a continuing unit.

842. Defendant Actavis and the other members of the Androderm DTC Enterprise created and maintained systematic links for the common purpose of gaining revenue from marketing Androderm for on- and off-label uses. Each of the members of the Androderm DTC Enterprise received substantial revenue from marketing Androderm. Such revenue was exponentially greater than it would have been if Androderm were marketed appropriately.

843. The Androderm DTC Enterprise has a hub and spoke organizational, decision-making structure, with Defendant Actavis serving as the hub.

844. All members of the Androderm DTC Enterprise were aware of Defendant Actavis' control over the activities of the Androderm DTC Enterprise. Furthermore, each member of the Androderm DTC Enterprise benefited from the existence of the other members.

845. The Androderm DTC Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, distributed, sold, and provided Androderm to thousands of individuals and entities throughout the United States.

846. Defendant Actavis has exerted control over the Androderm DTC Enterprise and has managed its affairs through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), and § 1952 (use of interstate facilities to conduct unlawful activity).

847. Defendant Actavis' use of, or causation of the use of, the mails and wires to perpetrate its fraud through the Androderm DTC Enterprise involved hundreds of

communications including, but not limited to: (a) marketing materials and advertisements aimed at patients that misrepresented that Androderm was safe and effective for off-label uses for which the drug was not legitimately proven safe and effective; (b) communications with patients including Plaintiff's and Class Members' participants and their dependents, inducing payments for Androderm to be made based on misrepresentations concerning its risks and benefits; and (c) receiving the proceeds of its improper scheme. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the Defendant Actavis throughout the Class Period consisted of at least two of the predicate acts within a ten year period.

848. In addition, Defendant Actavis' corporate headquarters have communicated by United States mail, telephone, and facsimile with various local district managers, medical liaisons, and sales representatives in order to use the Androderm DTC Enterprise to carry out its schemes to obtain money by means of false and fraudulent pretenses, representations, and omissions.

849. Further, Defendant Actavis has traveled in interstate or foreign commerce or used the mail and facilities in interstate or foreign commerce, with the intent to distribute the proceeds of the unlawful activity described above or otherwise promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on of the unlawful activity described above.

850. Defendant Actavis' racketeering activities related to the Androderm DTC Enterprise amounted to a common course of conduct intended to deceive and harm Plaintiff and the Class Members. Each racketeering activity was related, had similar purposes, involved the same or similar members and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. Defendant Actavis' racketeering activities

are part of its ongoing businesses and constitute a continuing threat to the property of Plaintiff and the Class Members.

851. Defendant Actavis' repeated use of the Androderm DTC Enterprise to implement and carry out the fraudulent schemes constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. §§ 1961(5) and 1962(c). Through that pattern of racketeering activity, Defendant Actavis conducted and participated in the conduct of the affairs of the Androderm DTC Enterprise.

852. Plaintiff and the Class Members have been directly injured in their business and property by reason of Defendant Actavis' violations of 18 U.S.C. § 1962(c) in that the pattern of racketeering activity that Defendant Actavis used to conduct the affairs of the Androderm DTC Enterprise directly and proximately caused them to spend excessive, ascertainable sums of money for the purchase, payment, or reimbursement of Androderm prescriptions that would not have been purchased, paid, or reimbursed if Defendant Actavis had not conducted or participated in the conduct of the affairs of the Androderm DTC Enterprise through a pattern of racketeering activity. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for Androderm, having received a product or prescription (Androderm) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses.

853. Plaintiff and the Class Members have also been directly injured in their business and property by reason of Defendant Actavis' violations of 18 U.S.C. § 1962(c) in that the pattern of racketeering activity that it used to conduct the affairs of the Androderm DTC Enterprise directly and proximately caused Plaintiff and the Class Members to spend excessive, ascertainable sums of money for the purchase or reimbursement of Androderm sold at a falsely

inflated price that would have been significantly lower if Defendant Actavis had not conducted or participated in the conduct of the affairs of the Androderm DTC Enterprise through a pattern of racketeering activity.

854. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Defendant Actavis' scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the Defendant Actavis' RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

855. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant Actavis is jointly and severally liable to Plaintiff and the Class Members for three times the damages they have sustained, punitive damages, plus the cost of this suit, including reasonable attorney's fees.

FIFTEENTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(c)
(The Fortesta DTC Enterprise – Against Defendant Endo)

856. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

857. Defendant Endo participated in the conduct of the affairs of the Fortesta DTC Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

858. The Fortesta DTC Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendant Endo, including its employees and agents, the marketing firms and publication firms that Defendant Endo associated with to market Fortesta

directly to patients, and the web designers who created websites to promote unfounded uses directly to consumers.

859. Defendant Endo is a RICO "person" distinct from the Fortesta DTC Enterprise.

860. Defendant Endo used the Fortesta DTC Enterprise to carry out its scheme to obtain money by means of false and fraudulent pretenses, representations, and omissions.

861. The Fortesta DTC Enterprise is an ongoing organization that functions as a continuing unit.

862. Defendant Endo and the other members of the Fortesta DTC Enterprise created and maintained systematic links for the common purpose of gaining revenue from marketing Fortesta for on- and off-label uses. Each of the members of the Fortesta DTC Enterprise received substantial revenue from marketing Fortesta. Such revenue was exponentially greater than it would have been if Fortesta were marketed appropriately.

863. The Fortesta DTC Enterprise has a hub and spoke organizational, decision-making structure, with Defendant Endo serving as the hub.

864. All members of the Fortesta DTC Enterprise were aware of Defendant Endo's control over the activities of the Fortesta DTC Enterprise. Furthermore, each member of the Fortesta DTC Enterprise benefited from the existence of the other members.

865. The Fortesta DTC Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, distributed, sold, and provided Fortesta to thousands of individuals and entities throughout the United States.

866. Defendant Endo has exerted control over the Fortesta DTC Enterprise and has managed its affairs through a pattern of racketeering activity that includes acts indictable under

18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), and § 1952 (use of interstate facilities to conduct unlawful activity).

867. Defendant Endo's use of, or causation of the use of, the mails and wires to perpetrate its fraud through the Fortesta DTC Enterprise involved hundreds of communications including, but not limited to: (a) marketing materials and advertisements aimed at patients that misrepresented that Fortesta was safe and effective for off-label uses for which the drug was not legitimately proven safe and effective; (b) communications with patients including Plaintiff's and Class Members' participants and their dependents, inducing payments for Fortesta to be made based on misrepresentations concerning its risks and benefits; and (c) receiving the proceeds of its improper scheme. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by the Defendant Endo throughout the Class Period consisted of at least two of the predicate acts within a ten year period.

868. In addition, Defendant Endo's corporate headquarters have communicated by United States mail, telephone, and facsimile with various local district managers, medical liaisons, and sales representatives in order to use the Fortesta DTC Enterprise to carry out its schemes to obtain money by means of false and fraudulent pretenses, representations, and omissions.

869. Further, Defendant Endo has traveled in interstate or foreign commerce or used the mail and facilities in interstate or foreign commerce, with the intent to distribute the proceeds of the unlawful activity described above or otherwise promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on of the unlawful activity described above.

870. Defendant Endo's racketeering activities related to the Fortesta DTC Enterprise amounted to a common course of conduct intended to deceive and harm Plaintiff and the Class Members. Each racketeering activity was related, had similar purposes, involved the same or similar members and methods of commission, and had similar results affecting similar victims, including Plaintiff and the Class Members. Defendant Endo's racketeering activities are part of its ongoing businesses and constitute a continuing threat to the property of Plaintiff and the Class Members.

871. Defendant Endo's repeated use of the Fortesta DTC Enterprise to implement and carry out the fraudulent schemes constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. §§ 1961(5) and 1962(c). Through that pattern of racketeering activity, Defendant Endo conducted and participated in the conduct of the affairs of the Fortesta DTC Enterprise.

872. Plaintiff and the Class Members have been directly injured in their business and property by reason of Defendant Endo's violations of 18 U.S.C. § 1962(c) in that the pattern of racketeering activity that Defendant Endo used to conduct the affairs of the Fortesta DTC Enterprise directly and proximately caused them to spend excessive, ascertainable sums of money for the purchase, payment, or reimbursement of Fortesta prescriptions that would not have been purchased, paid, or reimbursed if Defendant Endo had not conducted or participated in the conduct of the affairs of the Fortesta DTC Enterprise through a pattern of racketeering activity. Plaintiff and the Class Members suffered direct consequential and concrete financial loss flowing from the injury to their property by having overpaid for Fortesta, having received a product or prescription (Fortesta) that was worth less than what they paid for it, and thereby suffered out-of-pocket losses.

873. Plaintiff and the Class Members have also been directly injured in their business and property by reason of Defendant Endo's violations of 18 U.S.C. § 1962(c) in that the pattern of racketeering activity that it used to conduct the affairs of the Fortesta DTC Enterprise directly and proximately caused Plaintiff and the Class Members to spend excessive, ascertainable sums of money for the purchase or reimbursement of Fortesta sold at a falsely inflated price that would have been significantly lower if Defendant Endo had not conducted or participated in the conduct of the affairs of the Fortesta DTC Enterprise through a pattern of racketeering activity.

874. Plaintiff's and Class members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; their injuries were a foreseeable and natural consequence of the Defendant Endo's scheme; there is no difficulty posed by having to apportion damages among Class members with different standing or different levels of injury because there are no other injured parties besides the Plaintiff and the Class Members in this case, who are the parties directly injured by the Defendant Endo's RICO violations; and there are no others, more directly injured, that could vindicate the Plaintiff's and Class members' claims.

875. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant Endo is jointly and severally liable to Plaintiff and the Class Members for three times the damages they have sustained, punitive damages, plus the cost of this suit, including reasonable attorney's fees.

SIXTEENTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(d)
Conspiring to Violate 18 U.S.C. § 1962(c)
(Civil RICO Conspiracy Against the AbbVie Defendants)

876. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

877. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

878. The AbbVie Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the AndroGel Peer Selling Enterprise, the AndroGel Publication Enterprise, and the AndroGel DTC Enterprise described previously through a pattern of racketeering activity that directly caused injuries to the Plaintiff's and Class members' business or property within the meaning 18 U.S.C. § 1964(c). The corporate defendants conspired with, *inter alia*, publicists, sales representatives, medical professionals, academics and other intermediaries to promote AndroGel and suppress information about the harms known to result from AndroGel use.

879. The AbbVie Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class Members of money.

880. The nature of the above-described AbbVie Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracies gives rise to an inference that they not only agreed to the objective of an 18 U.S.C.§ 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity. In other words, the AbbVie Defendants adopted the goal of furthering or facilitating the conspiracy, and were aware of the essential nature and scope of the Enterprise and intended to participate in it.

881. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and the Class Members have been and are continuing to be injured in their business or property as set forth more fully above.

882. The AbbVie Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts: a) multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342; b) multiple instances of mail fraud violation of 18 U.S.C §§ 1341 and 1346; c) multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and d) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

883. The AbbVie Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue.

884. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have paid hundreds of millions of dollars for AndroGel that they would not have paid had the AbbVie Defendants not conspired to violate 18 U.S.C. § 1962(c).

885. Injuries suffered by Plaintiff and members of the Class were directly and proximately caused by the AbbVie Defendants' racketeering activity as described above. As also set forth above, these injuries would not have occurred but for the AbbVie Defendants' RICO predicate act violations, and they involved concrete financial losses to the Plaintiff and the Class Members.

886. Patients, physicians, PBMs, P&T Committee members, and TPPs, including Plaintiff and the Class, directly relied on the racketeering activities of the AbbVie Defendants'

and the AndroGel Peer Selling Enterprise, the AndroGel Publication Enterprise, and the AndroGel DTC Enterprise. Plaintiff and the Class Members, both directly and indirectly, relied on the representations as to the efficacy and safety of AndroGel as promoted by the AbbVie Defendants. Because the AbbVie Defendants controlled all knowledge of the tests upon which the claims of AndroGel's efficacy and safety were based, all Class Members, as well as other members of the medical and consuming public were obligated to rely on the AbbVie Defendants' representations about AndroGel. Further, the AbbVie Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about AndroGel.

887. By virtue of these violations of 18 U.S.C. § 1962(d), the AbbVie Defendants are liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

888. By reason of the foregoing, and as a direct and proximate result of the AbbVie Defendants' fraudulent misrepresentations, Plaintiff and the Class Members have suffered damages. Plaintiff and the Class Members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

889. By reason of the foregoing, Plaintiff and the Class Members have been damaged as against the AbbVie Defendants in a sum that exceeds the jurisdiction of all lower courts.

SEVENTEENTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(d)
Conspiring to Violate 18 U.S.C. § 1962(c)
(Civil RICO Conspiracy Against Defendant Auxilium)

890. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

891. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

892. Defendant Auxilium has violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Testim and Testopel Peer Selling Enterprise, the Testim and Testopel Publication Enterprise, and the Testim and Testopel DTC Enterprise described previously through a pattern of racketeering activity that directly caused injuries to the Plaintiff's and Class members' business or property within the meaning 18 U.S.C. § 1964(c). The corporate defendants conspired with, *inter alia,* publicists, sales representatives, medical professionals, academics and other intermediaries to promote Testim and Testopel and suppress information about the harms known to result from Testim and Testopel use.

893. Defendant Auxilium's co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class Members of money.

894. The nature of the above-described Defendant Auxilium and its co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracies gives rise to an inference that they not only agreed to the objective of an 18 U.S.C.§ 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity. In other words, the Defendant Auxilium adopted the goal of furthering or facilitating the conspiracy, and was aware of the essential nature and scope of the Enterprise and intended to participate in it.

895. As a direct and proximate result of Defendant Auxilium and its co-conspirator's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and the Class Members have been and are continuing to be injured in their business or property as set forth more fully above.

896. Defendant Auxilium and its co-conspirators sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts: a) multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342; b) multiple instances of mail fraud violation of 18 U.S.C §§ 1341 and 1346; c) multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and d) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

897. The violations by Defendant Auxilium and its co-conspirators of the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have paid hundreds of millions of dollars for Testim and Testopel that they would not have made had Defendant Auxilium and its co-conspirators not conspired to violate 18 U.S.C. § 1962(c).

898. Injuries suffered by Plaintiff and members of the Class were directly and proximately caused by Defendant Auxilium's racketeering activity as described above. As also set forth above, these injuries would not have occurred but for the Defendant Auxilium's RICO predicate act violations, and they involved concrete financial losses to the Plaintiff and the Class Members.

899. Patients, physicians, PBMs, P&T Committee members, and TPPs, including Plaintiff and the Class, directly relied on the racketeering activities of Defendant Auxilium and

the Testim and Testopel Peer Selling Enterprise, the Testim and Testopel Publication Enterprise, and the Testim and Testopel DTC Enterprise. Plaintiff and the Class Members, both directly and indirectly, relied on the representations as to the efficacy and safety of Testim and Testopel as promoted by Defendant Auxilium. Because Defendant Auxilium controlled all knowledge of the tests upon which the claims of Testim's and Testopel's efficacy and safety were based, Plaintiff and the Class Members, as well as other members of the medical and consuming public were obligated to rely on Defendant Auxilium's representations about Testim and Testopel. Further, Defendant Auxilium perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Testim and Testopel.

900. By virtue of these violations of 18 U.S.C. § 1962(d), Defendant Auxilium is jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

901. By reason of the foregoing, and as a direct and proximate result of Defendant Auxilium's fraudulent misrepresentations, Plaintiff and the Class Members have suffered damages. Plaintiff and the Class Members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

902. By reason of the foregoing, Plaintiff and the Class Members have been damaged as against Defendant Auxilium in a sum that exceeds the jurisdiction of all lower courts.

EIGHTEENTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(d)
Conspiring to Violate 18 U.S.C. § 1962(c)
(Civil RICO Conspiracy Against Defendant Eli Lilly)

903. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

904. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

905. Defendant Eli Lilly has violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Axiron Peer Selling Enterprise, the Axiron Publication Enterprise, and the Axiron DTC Enterprise described previously through a pattern of racketeering activity that directly caused injuries to the Plaintiff's and Class members' business or property within the meaning 18 U.S.C. § 1964(c). The corporate defendants conspired with, *inter alia*, publicists, sales representatives, medical professionals, academics and other intermediaries to promote Axiron and suppress information about the harms known to result from Axiron use.

906. Defendant Eli Lilly's co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class Members of money.

907. The nature of the above-described Defendant Eli Lilly and its co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracies gives rise to an inference that they not only agreed to the objective of an 18 U.S.C.§ 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity. In other words, the Defendant Eli Lilly adopted the goal of furthering or facilitating the conspiracy, and was aware of the essential nature and scope of the Enterprise and intended to participate in it.

908. As a direct and proximate result of Defendant Eli Lilly's and its co-conspirator's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and the Class Members have been and are continuing to be injured in their business or property as set forth more fully above.

909. Defendant Eli Lilly and its co-conspirators sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts: a) multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342; b) multiple instances of mail fraud violation of 18 U.S.C §§ 1341 and 1346; c) multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and d) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

910. The violations by Defendant Eli Lilly and its co-conspirators of the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have paid hundreds of millions of dollars for Axiron that they would not have paid had Defendant Eli Lilly and its co-conspirators not conspired to violate 18 U.S.C. § 1962(c).

911. Injuries suffered by Plaintiff and members of the Class were directly and proximately caused by Defendant Eli Lilly's racketeering activity as described above. As also set forth above, these injuries would not have occurred but for the Defendant Eli Lilly's RICO predicate act violations, and they involved concrete financial losses to the Plaintiff and the Class Members.

912. Patients, physicians, PBMs, P&T Committee members, and TPPs, including Plaintiff and the Class, directly relied on the racketeering activities of Defendant Eli Lilly and the

Axiron Peer Selling Enterprise, the Axiron Publication Enterprise, and the Axiron DTC Enterprise. Plaintiff and the Class Members, both directly and indirectly, relied on the representations as to the efficacy and safety of Axiron as promoted by Defendant Eli Lilly. Because Defendant Eli Lilly controlled all knowledge of the tests upon which the claims of Axiron's efficacy and safety were based, Plaintiff and the Class Members, as well as other members of the medical and consuming public were obligated to rely on Defendant Eli Lilly's representations about Axiron. Further, Defendant Eli Lilly perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Axiron.

913. By virtue of these violations of 18 U.S.C. § 1962(d), Defendant Eli Lilly is jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

914. By reason of the foregoing, and as a direct and proximate result of Defendant Eli Lilly's fraudulent misrepresentations, Plaintiff and the Class Members have suffered damages. Plaintiff and the Class Members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

915. By reason of the foregoing, Plaintiff and the Class Members have been damaged as against Defendant Eli Lilly in a sum that exceeds the jurisdiction of all lower courts.

NINETEENTH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(d)
Conspiring to Violate 18 U.S.C. § 1962(c)
(Civil RICO Conspiracy Against Defendant Actavis)

916. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

917. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

918. Defendant Actavis has violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Androderm Peer Selling Enterprise, the Androderm Publication Enterprise, and the Androderm DTC Enterprise described previously through a pattern of racketeering activity that directly caused injuries to the Plaintiff's and Class members' business or property within the meaning 18 U.S.C. § 1964(c). The corporate defendants conspired with, *inter alia*, publicists, sales representatives, medical professionals, academics and other intermediaries to promote Androderm and suppress information about the harms known to result from Androderm use.

919. Defendant Actavis' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class Members of money.

920. The nature of the above-described Defendant Actavis and its co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracies gives rise to an inference that they not only agreed to the objective of an 18 U.S.C.§ 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity. In other words, the Defendant Actavis adopted the goal of furthering or facilitating the conspiracy, and was aware of the essential nature and scope of the Enterprise and intended to participate in it.

921. As a direct and proximate result of Defendant Actavis and its co-conspirator's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and the Class Members have been and are continuing to be injured in their business or property as set forth more fully above.

922. Defendant Actavis and its co-conspirators sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts: a) multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342; b) multiple instances of mail fraud violation of 18 U.S.C §§ 1341 and 1346; c) multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and d) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

923. The violations by Defendant Actavis and its co-conspirators of the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have paid hundreds of millions of dollars for Androderm that they would not have paid had Defendant Actavis and its co-conspirators not conspired to violate 18 U.S.C. § 1962(c).

924. Injuries suffered by Plaintiff and members of the Class were directly and proximately caused by Defendant Actavis' racketeering activity as described above. As also set forth above, these injuries would not have occurred but for the Defendant Actavis' RICO predicate act violations, and they involved concrete financial losses to the Plaintiff and the Class Members.

925. Patients, physicians, PBMs, P&T Committee members, and TPPs, including Plaintiff and the Class, directly relied on the racketeering activities of Defendant Actavis and the

Androderm Peer Selling Enterprise, the Androderm Publication Enterprise, and the Androderm DTC Enterprise. Plaintiff and the Class Members, both directly and indirectly, relied on the representations as to the efficacy and safety of Androderm as promoted by Defendant Actavis. Because Defendant Actavis controlled all knowledge of the tests upon which the claims of Androderm's efficacy and safety were based, Plaintiff and the Class Members, as well as other members of the medical and consuming public were obligated to rely on Defendant Actavis' representations about Androderm. Further, Defendant Actavis perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Androderm.

926. By virtue of these violations of 18 U.S.C. § 1962(d), Defendant Actavis is jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

927. By reason of the foregoing, and as a direct and proximate result of Defendant Actavis' fraudulent misrepresentations, Plaintiff and the Class Members have suffered damages. Plaintiff and the Class Members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

928. By reason of the foregoing, Plaintiff and the Class Members have been damaged as against Defendant Actavis in a sum that exceeds the jurisdiction of all lower courts.

TWENTIETH CLAIM FOR RELIEF
Violation of 18 U.S.C. § 1962(d)
Conspiring to Violate 18 U.S.C. § 1962(c)
(Civil RICO Conspiracy Against Defendant Endo)

929. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

930. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

931. Defendant Endo has violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Fortesta Peer Selling Enterprise, the Fortesta Publication Enterprise, and the Fortesta DTC Enterprise described previously through a pattern of racketeering activity that directly caused injuries to the Plaintiff's and Class members' business or property within the meaning 18 U.S.C. § 1964(c). The corporate defendants conspired with, *inter alia*, publicists, sales representatives, medical professionals, academics and other intermediaries to promote Fortesta and suppress information about the harms known to result from Fortesta use.

932. Defendant Endo's co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class Members of money.

933. The nature of the above-described Defendant Endo and its co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracies gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity. In other words, the Defendant Endo adopted the goal of furthering or facilitating the conspiracy, and was aware of the essential nature and scope of the Enterprise and intended to participate in it.

934. As a direct and proximate result of Defendant Endo and its co-conspirator's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and the Class Members have been and are continuing to be injured in their business or property as set forth more fully above.

935. Defendant Endo and its co-conspirators sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts: a) multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342; b) multiple instances of mail fraud violation of 18 U.S.C §§ 1341 and 1346; c) multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and d) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

936. The violations by Defendant Endo and its co-conspirators of the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have paid hundreds of millions of dollars for Fortesta that they would not have made had Defendant Endo and its co-conspirators not conspired to violate 18 U.S.C. § 1962(c).

937. Injuries suffered by Plaintiff and members of the Class were directly and proximately caused by Defendant Endo's racketeering activity as described above. As also set forth above, these injuries would not have occurred but for the Defendant Endo's RICO predicate act violations, and they involved concrete financial losses to the Plaintiff and the Class Members.

938. Patients, physicians, PBMs, P&T Committee members, and TPPs, including Plaintiff and the Class, directly relied on the racketeering activities of Defendant Endo and the

Fortesta Peer Selling Enterprise, the Fortesta Publication Enterprise, and the Fortesta DTC Enterprise. Plaintiff and the Class Members, both directly and indirectly, relied on the representations as to the efficacy and safety of Fortesta as promoted by Defendant Endo. Because Defendant Endo controlled all knowledge of the tests upon which the claims of Fortesta's efficacy and safety were based, Plaintiff and the Class Members, as well as other members of the medical and consuming public were obligated to rely on Defendant Endo's representations about Fortesta. Further, Defendant Endo perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Fortesta.

939. By virtue of these violations of 18 U.S.C. § 1962(d), Defendant Endo is jointly and severally liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

940. By reason of the foregoing, and as a direct and proximate result of Defendant Endo's fraudulent misrepresentations, Plaintiff and the Class Members have suffered damages. Plaintiff and the Class Members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

941. By reason of the foregoing, Plaintiff and the Class Members have been damaged as against Defendant Endo in a sum that exceeds the jurisdiction of all lower courts.

TWENTY-FIRST CLAIM FOR RELIEF
Violation of Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, et seq.
(AbbVie Defendants)

942. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

943. The AbbVie Defendants engaged in deceptive or unfair acts or practices in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815

ILCS 505/1, *et seq.* when the AbbVie Defendants knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, and usefulness of AndroGel, and through Defendants' execution of the Peer Selling, Publication, and DTC Enterprises.

944. The AbbVie Defendants' deceptive or unfair acts were specifically designed to induce Plaintiff and the Class Members to pay for excessive amounts of AndroGel, in reliance thereon.

945. The AbbVie Defendants' deceptive or unfair acts occurred during a course of conduct involving trade or commerce.

946. The AbbVie Defendants' deceptive or unfair acts were performed with malice, evil motive, or reckless indifference toward the rights of others. The AbbVie Defendants' acts are thus outrageous and warrant an award of punitive or exemplary damages pursuant to the ICFA.

947. Furthermore, the AbbVie Defendants' ICFA violations warrant treatment as a national class, on account of the fact that the AndroGel Peer Selling, Publication, and DTC Enterprises, as well as the AbbVie Defendants' fraudulent marketing of AndroGel, was and is executed principally and substantially from Defendants' Illinois headquarters on a national level.

948. As a result of Defendants' violations of ICFA, Defendants have been unjustly enriched at the expense of Plaintiff and the Class Members. Absent Defendants' unlawful, fraudulent and deceptive conduct, Plaintiff and the Class Members would not have paid excessive amounts for AndroGel.

949. The deceptive acts of Defendants have injured and present a continuing injury and threat of injury to Plaintiff and the Class Members in that Defendants' conduct has proximately caused Plaintiff and the Class Members to pay for excessive amounts of AndroGel.

950. As alleged herein, Defendants have been unjustly enriched as a result of this unfair competition. Plaintiff and the Class Members are accordingly entitled to actual damages, equitable relief including restitution and/or disgorgement of all revenues, earnings, profits, compensation and benefits which may have been obtained by Defendants as a result of such business acts or practices, and punitive or exemplary damages, in addition to any other remedy allowable at law.

TWENTY-SECOND CLAIM FOR RELIEF
Violations of the Consumer Protection Laws of the Remaining Forty-Nine (49) States, the District of Columbia, and Puerto Rico
(AbbVie Defendants)

951. The AbbVie Defendants each engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in knowing violation of any and all state consumer protection statutes when the AbbVie Defendants knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, usefulness and appropriate dosages of AndroGel.

952. The AbbVie Defendants' unfair or deceptive acts or practices were specifically designed to and did induce Plaintiff and the Class Members to pay for excessive amounts of AndroGel.

953. The AbbVie Defendants have violated the consumer protection statutes of the remaining forty nine (49) states, the District of Columbia, and the Commonwealth of Puerto Rico, as follows:

a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq*.;

b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq*.;

c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

d) Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;

e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

rr) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

954. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and the Class Members have suffered damages in an amount to be proved at trial by paying for excessive amounts of AndroGel in all aforementioned jurisdictions.

TWENTY-THIRD CLAIM FOR RELIEF
Violations of Illinois's Insurance Fraud Statute, 720 ILCS 5/17-10.5
(AbbVie Defendants)

955. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

956. The Illinois Insurance Fraud Statute, 720 ILCS 5/17-10.5 provides, in pertinent part, that a person commits insurance fraud when he or she:

> knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property.

957. Operating principally and substantially from the State of Illinois, the AbbVie Defendants knowingly, and by deception, caused false AndroGel claims to be made on policies of insurance issued by Plaintiff and the Class Members within and outside of the State of Illinois, thereby obtaining, and attempting to obtain, control over the property of Plaintiff and the Class Members, intended to deprive Plaintiff and the Class Members of that property permanently. Plaintiff and the Class Members have been fraudulently caused to incur damages by having to permanently pay significant sums of money to the AbbVie Defendants.

958. The AbbVie Defendants' deception included, but is not limited to: (a) the AbbVie Defendants' false representations and omissions concerning the safety and efficacy profile of AndroGel for off-label uses, causing prescriptions to be written, filled, and reimbursed which otherwise would not have been written, filled, and reimbursed; (b) the actions perpetrated by Defendants and participating vendors and physicians as part of the Peer Selling, Publication, and DTC Enterprises for AndroGel; (c) Defendants' deliberate causing of prescription forms, such as

prior authorization forms, to be submitted so as to conceal from Plaintiff and the Class Members that AndroGel prescriptions were being written for off-label uses; (d) Defendants' targeting of Plaintiff and the Class Members, and P&T Committees and PBMs, and making false representations and omissions concerning the safety and efficacy profile of AndroGel for off-label uses.

959. The thousands of AndroGel claims that AbbVie caused to be submitted to Plaintiff and the Class Members constituted and constitute "false claims" within the meaning of 720 ILCS 5/17-0.5.

960. As a result of the AbbVie Defendants' violations of the Illinois Insurance Fraud Statute, 720 ILCS 5/17-10.5, the AbbVie Defendants are liable to Plaintiff and the Class Members within and outside Illinois in an amount equal to either 3 times the value of the property wrongfully obtained from Plaintiff and the Class Members or, if no property was wrongfully obtained, twice the value of the property attempted to be obtained, whichever amount is greater, plus reasonable attorney's fees.

TWENTY-FOURTH CLAIM FOR RELIEF
Violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("PUTPCPL"), 73 Pa. Stat. § 201-1, *et seq.*
(Defendant Auxilium)

961. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

962. Plaintiff brings this count on behalf of themselves and a national class of Testim and Testopel-reimbursing TPP Class Members.

963. Defendant Auxilium engaged in fraudulent and deceptive conduct in violation of PUTPCPL, 73 Pa. Stat. § 201-1, *et seq.*, when Defendant Auxilium knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, and usefulness of Testim and

Testopel, and through Defendant's execution of the Testim and Testopel Peer Selling, Publication, and DTC Enterprises.

964. As a direct and proximate result of Defendant Auxilium's fraudulent and deceptive conduct, Plaintiff and the Class Members were injured by purchasing, paying for, and reimbursing for excessive amounts of Testim and Testopel, and by making favorable formulary placements for Testim and Testopel.

965. In addition to actual damages, Plaintiff and the Class Members are entitled to declaratory and injunctive relief, as well as attorney's fees and costs, pursuant to 73 Pa. Stat. § 201-9.2.

TWENTY-FIFTH CLAIM FOR RELIEF
Violations of the Consumer Protection Laws of the Remaining Forty-Nine (49) States, the District of Columbia, and Puerto Rico
(Defendant Auxilium)

966. Defendant Auxilium engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in knowing violation of any and all state consumer protection statutes when Defendant Auxilium knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, usefulness and appropriate dosages of Testim and Testopel.

967. Defendant Auxilium's unfair or deceptive acts or practices were specifically designed to and did induce Plaintiff and the Class Members to pay for excessive amounts of Testim and Testopel.

968. Defendant Auxilium has violated the consumer protection statutes of the remaining forty nine (49) states, the District of Columbia, and the Commonwealth of Puerto Rico, as follows:

a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

d) Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;

e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS 505/1, *et seq*.

n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq*.;

v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

rr) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

969. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and the Class Members have suffered damages in an amount to be proved at trial by paying for excessive amounts of Testim and Testopel in all aforementioned jurisdictions.

TWENTY-SIXTH CLAIM FOR RELIEF
Violations of Pennsylvania's Insurance Fraud Statue - 18 Pa. C.S.A. § 4117
(Defendant Auxilium)

970. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

971. Plaintiff assert this Pennsylvania insurance fraud cause of action, pursuant to 18 Pa. C.S.A. § 4117(g), against Defendant Auxilium on behalf of TPP Class Members nationwide.

972. The Pennsylvania Insurance Fraud Statute, 18 Pa. C.S.A. § 4117(a)(2) provides that a person commits an offense if he or she:

> Knowingly and with the intent to defraud any insurer or self-insured, presents or causes to be presented to an insurer or self-insured any statement forming a part of, or in support of a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim.

973. Defendant Auxilium knowingly and with the intent to defraud Plaintiff and TPP Class Members, engaged in a pattern of causing to be presented to Plaintiff and TPP Class Members false, incomplete, and misleading insurance claim information.

974. Defendant Auxilium's fraudulent schemes set forth in detail in the Testim and Testopel Peer Selling, Publication, and DTC Enterprises, as well as Defendant Auxilium's targeting of TPPs caused Plaintiff and the Class Members to be overbilled for Testim and Testopel.

975. Each of Defendant Auxilium's schemes and actions undertaken as a part thereof,

Enterprises and actions undertaken as a part thereof, and actions targeting TPPs constitutes "Insurance Fraud" within the meaning of 18 Pa. C.S.A. § 4117(a). Collectively, these violations constitute a pattern of insurance fraud within the meaning of 18 Pa. C.S.A. § 4117(g).

976. Defendant Auxilium knowingly benefitted, directly or indirectly, from the proceeds derived from thousands of violations of 18 Pa. C.S.A. § 4117, due to the assistance, conspiracy or urging of the various participants in the Testim and Testopel Peer Selling, Publication, and DTC Enterprises.

977. Much of the wrongful, deceptive, and unfair conduct detailed with regard to Defendant Auxilium's fraudulent marketing of Testim and Testopel took place principally from Pennsylvania and/or caused injury to Plaintiff and the Class Members within and outside of Pennsylvania.

978. By reason of the foregoing, and as a proximate cause of said pattern of fraudulent activity and its acts committed in furtherance thereof, Plaintiff have suffered grievous injury and have been damaged.

979. Pursuant to the civil action provisions of 18 Pa. C.S.A. § 4117(g), Plaintiff and Class Member TPPs nationally are entitled to compensatory damages, reasonable investigations expenses, costs of suit, and attorney fees. Moreover, Defendant Auxilium engaged in a pattern of violating 18 Pa. C.S.A. § 4117, and Plaintiff and Class Member TPPs nationally are entitled to treble damages.

TWENTY-SEVENTH CLAIM FOR RELIEF
Violations of Indiana's Deceptive Consumer Sales Act ("IDCSA") – Ind. Code § 24-5-0.5 et seq.
(Defendant Eli Lilly)

980. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

981. Plaintiff brings this count on behalf of themselves and a national class of Axiron-reimbursing TPPs.

982. Defendant Eli Lilly engaged in fraudulent and deceptive conduct in violation of IDCSA, Ind. Code § 24-5-0.5-3 *et seq.*, when Defendant Eli Lilly knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, and usefulness of Axiron for off-label and unapproved uses, and through Defendant's execution of the Axiron Peer Selling, Publication, and DTC Enterprises.

983. As a direct and proximate result of Defendant Eli Lilly's fraudulent and deceptive conduct, Plaintiff and the Class Members were injured by purchasing, paying for, and reimbursing for excessive amounts of Axiron, and by making favorable formulary placements for Axiron.

984. Defendant Eli Lilly maintains its corporate headquarters and principal place of business in Indiana. Defendant Lilly's unlawful and deceptive practices emanated from its corporate headquarters in Indiana. Defendant Lilly's corporate headquarters communicated with Defendant Lilly's nationwide personnel and with the vendor and physician participants in the Axiron Peer Selling, Publication, and DTC Enterprises, which were all executed principally from Defendant Lilly's Indianapolis, Indiana headquarters.

985. Defendant Lilly received the proceeds of its unlawful and deceptive scheme in Indiana.

986. Plaintiff and the Class Members purchased Axiron for the personal or household use of their beneficiaries.

987. As the state where Defendant Lilly's unlawful and deceptive scheme was principally executed, Indiana has the strongest nexus to the unlawful and deceptive conduct and the greatest interests in punishment and deterrence.

988. In addition to actual and treble damages, Plaintiff and the Class Members are entitled to declaratory and injunctive relief, as well as attorney's fees and costs, pursuant to Ind. Code § 24-5-0.5-4.

TWENTY-EIGHTH CLAIM FOR RELIEF
Violations of the Consumer Protection Laws of the Remaining Forty-Nine (49) States, the District of Columbia, and Puerto Rico
(Defendant Lilly)

989. Defendant Lilly engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in knowing violation of any and all state consumer protection statutes when Defendant Lilly knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, usefulness and appropriate dosages of Axiron.

990. Defendant Lilly's unfair or deceptive acts or practices were specifically designed to and did induce Plaintiff and the Class Members to pay for excessive amounts of Axiron.

991. Defendant Lilly has violated the consumer protection statutes of the remaining forty nine (49) states, the District of Columbia, and the Commonwealth of Puerto Rico, as follows:

a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

d) Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;

e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS 505/1, *et seq.*

m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

rr) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

992. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and the Class Members have suffered damages in an amount to be proved at trial by paying for excessive amounts of Axiron in all aforementioned jurisdictions.

TWENTY-NINTH CLAIM FOR RELIEF
Violations of New Jersey's Consumer Fraud Act ("NJCFA") –
N.J. Stat. Ann. § 56:8-1 et seq.
(Defendant Actavis)

993. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

994. Plaintiff brings this count on behalf of themselves and a national class of Androderm-reimbursing TPPs.

995. Defendant Actavis engaged in fraudulent and deceptive conduct in violation of NJCFA, N.J. Stat. Ann. § 56:8-1 *et seq.*, when Defendant Actavis knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, and usefulness of Androderm, and through Defendant's execution of the Androderm Peer Selling, Publication, and DTC Enterprises.

996. Defendant Actavis' fraudulent and deceptive acts were specifically designed to induce Plaintiff and the Class Members to pay for excessive amounts of Androderm, in reliance thereon.

997. As a direct and proximate result of Defendant Actavis' fraudulent and deceptive conduct, Plaintiff and the Class Members were injured by purchasing, consuming, and reimbursing for excessive amounts of Androderm, and by making favorable formulary placements for Androderm.

998. Defendant Actavis maintains its U.S. headquarters in New Jersey. Defendant Actavis' unlawful and deceptive practices emanated from its New Jersey-based U.S. headquarters. Defendant Actavis planned its national development, advertising, promotion, and marketing strategies of Androderm in New Jersey, and Androderm is manufactured in New Jersey. Defendant Actavis communicated from its New Jersey-based U.S. headquarters with its nationwide personnel and with the vendor and physician participants in the Androderm Peer

Selling, Publication, and DTC Enterprises, which were all executed principally from Defendant Actavis' New Jersey-based U.S. headquarters.

999. Defendant Actavis received the proceeds of its unlawful and deceptive scheme in New Jersey.

1000. Plaintiff and the Class Members purchased Androderm for the use of their beneficiaries.

1001. As the state where Defendant Actavis' unlawful and deceptive scheme was principally executed, New Jersey has the strongest nexus to the unlawful and deceptive conduct and the greatest interests in punishment and deterrence.

1002. In addition to actual damages, because they have suffered ascertainable losses due to Defendant Actavis' unlawful and deceptive scheme, Plaintiff and the Class Members are entitled to mandatory punitive trebling of damages, as well as declaratory and injunctive relief and attorney's fees and costs, pursuant to N.J. Stat. Ann. § 56:8-19.

THIRTIETH CLAIM FOR RELIEF
Violations of the Consumer Protection Laws of the Remaining Forty-Nine (49) States, the District of Columbia, and Puerto Rico
(Defendant Actavis)

1003. Defendant Actavis engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in knowing violation of any and all state consumer protection statutes when Defendant Actavis knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, usefulness and appropriate dosages of Androderm.

1004. Defendant Actavis' unfair or deceptive acts or practices were specifically designed to and did induce Plaintiff and the Class Members to pay for excessive amounts of Androderm.

1005. Defendant Actavis has violated the consumer protection statutes of the remaining forty nine (49) states, the District of Columbia, and the Commonwealth of Puerto Rico, as follows:

a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

d) Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;

e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS 505/1, *et seq.*

m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

rr) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

1006. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and the Class Members have suffered damages in an amount to be proved at trial by paying for excessive amounts of Androderm in all aforementioned jurisdictions.

THIRTY-FIRST CLAIM FOR RELIEF
Violations of New Jersey Insurance Fraud Prevention Act ("NJIFPA"),
N.J. Stat. Ann. § 17:33A, et seq.,
(Defendant Actavis)

1007. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

1008. Plaintiff assert this NJIFPA claim, pursuant to N.J. Stat. Ann. § 17:33A-4, against Defendant Actavis on behalf of TPP Class Members nationwide.

1009. Defendant Actavis knowingly and with the intent to defraud Plaintiff and TPP Class Members, engaged in a pattern of causing to be presented to Plaintiff and TPP Class Members materially false, incomplete, and misleading insurance claim information.

1010. Defendant Actavis' fraudulent schemes set forth in detail in the Peer Selling, Publication, and DTC Enterprises, as well as Defendant Actavis' targeting of TPPs caused Plaintiff and the Class Members to be overbilled for Androderm.

1011. Each of Defendant Actavis' schemes and actions undertaken as a part thereof, Enterprises and actions undertaken as a part thereof, and actions targeting TPPs constitutes

insurance fraud within the meaning of N.J. Stat. Ann. § 17:33A-4. Collectively, these violations constitute a pattern of insurance fraud within the meaning of N.J. Stat. Ann. § 17:33A-3.

1012. Defendant Actavis knowingly benefitted, directly or indirectly, from the proceeds derived from thousands of violations of N.J. Stat. Ann. § 17:33A-4, due to the assistance, conspiracy or urging of the various participants in the Androderm Peer Selling, Publication, and DTC Enterprises.

1013. Much of the wrongful, deceptive, and unfair conduct detailed with regard to Defendant Actavis' fraudulent marketing of Androderm took place principally from New Jersey and/or caused injury to Plaintiff and the Class Members within and outside of New Jersey.

1014. By reason of the foregoing, and as a proximate cause of said pattern of fraudulent activity and its acts committed in furtherance thereof, Plaintiff have suffered grievous injury and have been damaged.

1015. Pursuant to the civil action provisions of N.J. Stat. Ann. § 17:33A-7, Plaintiff and Class Member TPPs nationally are entitled to compensatory damages, reasonable investigations expenses, costs of suit, and attorney fees. Moreover, Defendant Actavis engaged in a pattern of violating N.J. Stat. Ann. § 17:33A-4, and Plaintiff and Class Member TPPs nationally are entitled to treble damages.

THIRTY-SECOND CLAIM FOR RELIEF
Violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("PUTPCPL"), 73 Pa. Stat. § 201-1, et seq.
(Defendant Endo)

1016. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

1017. Plaintiff brings this count on behalf of themselves and a national class of Fortesta-reimbursing TPPs.

1018. Defendant Endo engaged in fraudulent and deceptive conduct in violation of PUTPCPL, 73 Pa. Stat. § 201-1, *et seq.*, when Defendant Endo knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, and usefulness of Fortesta, and through Defendant's execution of the Fortesta Peer Selling, Publication, and DTC Enterprises.

1019. As a direct and proximate result of Defendant Endo's fraudulent and deceptive conduct, Plaintiff and the Class Members were injured by purchasing, paying for, and reimbursing for excessive amounts of Fortesta, and by making favorable formulary placements for Fortesta.

1020. In addition to actual damages, Plaintiff and the Class Members are entitled to declaratory and injunctive relief, as well as attorney's fees and costs, pursuant to 73 Pa. Stat. § 201-9.2. In addition, Plaintiff and the Class Members nationally request the Court exercise its discretionary authority in granting treble damages due to Defendant Endo's pattern of fraudulent and deceptive practices. 73 Pa. Stat. § 201-9.2(a).

THIRTY-THIRD CLAIM FOR RELIEF
Violations of the Consumer Protection Laws of the Remaining Forty-Nine (49) States, the District of Columbia, and Puerto Rico
(Defendant Endo)

1021. Defendant Endo engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in knowing violation of any and all state consumer protection statutes when Defendant Endo knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, usefulness and appropriate dosages of Fortesta.

1022. Defendant Endo's unfair or deceptive acts or practices were specifically designed to and did induce Plaintiff and the Class Members to pay for excessive amounts of Fortesta.

1023. Defendant Endo has violated the consumer protection statutes of the remaining forty nine (49) states, the District of Columbia, and the Commonwealth of Puerto Rico, as follows:

a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

d) Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;

e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS 505/1, *et seq.*

n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

rr) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

1024. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and the Class Members have suffered damages in an amount to be proved at trial by paying for excessive amounts of Fortesta in all aforementioned jurisdictions.

THIRTY-FOURTH CLAIM FOR RELIEF
Violations of Pennsylvania's Insurance Fraud Statue - 18 Pa. C.S.A. § 4117
(Defendant Endo)

1025. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

1026. Plaintiff assert this Pennsylvania insurance fraud cause of action, pursuant to 18 Pa. C.S.A. § 4117(g), against Defendant Endo on behalf of TPP Class Members nationwide.

1027. The Pennsylvania Insurance Fraud Statute, 18 Pa. C.S.A. § 4117(a)(2) provides that a person commits an offense if he or she:

> Knowingly and with the intent to defraud any insurer or self-insured, presents or causes to be presented to an insurer or self-insured any statement forming a part of, or in support of a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim.

1028. Defendant Endo knowingly and with the intent to defraud Plaintiff and TPP Class Members, engaged in a pattern of causing to be presented to Plaintiff and TPP Class Members false, incomplete, and misleading insurance claim information.

1029. Defendant Endo's fraudulent schemes set forth in detail in the Peer Selling, Publication, and DTC Enterprises, as well as Defendant Endo's targeting of TPPs caused Plaintiff and the Class Members to be overbilled for Fortesta.

1030. Each of Defendant Endo's schemes and actions undertaken as a part thereof, Enterprises and actions undertaken as a part thereof, and actions targeting TPPs constitutes "Insurance Fraud" within the meaning of 18 Pa. C.S.A. § 4117(a). Collectively, these violations constitute a pattern of insurance fraud within the meaning of 18 Pa. C.S.A. § 4117(g).

1031. Defendant Endo knowingly benefitted, directly or indirectly, from the proceeds derived from thousands of violations of 18 Pa. C.S.A. § 4117, due to the assistance, conspiracy or urging of the various participants in the Fortesta Peer Selling, Publication, and DTC Enterprises.

1032. Much of the wrongful, deceptive, and unfair conduct detailed with regard to Defendant Endo's fraudulent marketing of Fortesta took place principally from Pennsylvania and/or caused injury to Plaintiff and the Class Members within and outside of Pennsylvania.

1033. By reason of the foregoing, and as a proximate cause of said pattern of fraudulent activity and its acts committed in furtherance thereof, Plaintiff have suffered grievous injury and have been damaged.

1034. Pursuant to the civil action provisions of 18 Pa. C.S.A. § 4117(g), Plaintiff and Class Member TPPs nationally are entitled to compensatory damages, reasonable investigations expenses, costs of suit, and attorney fees. Moreover, Defendant Endo engaged in a pattern of violating 18 Pa. C.S.A. § 4117, and Plaintiff and Class Member TPPs nationally are entitled to treble damages.

THIRTY-FIFTH CLAIM FOR RELIEF
Common Law Fraud (All Defendants)

1035. Plaintiff repeats and realleges each of the preceding paragraphs, as if fully set forth herein.

1036. Plaintiff and Class Members assert common law fraud claims under against the AbbVie Defendants, Defendant Auxilium, Defendant Lilly, Defendant Actavis, and Defendant Endo.

1037. Defendants each knowingly made false representations or omissions of material fact for the purpose of inducing Plaintiff and the Class Members to act thereon when Defendants each knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness, and usefulness of AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, and made false representations and omissions of material fact with the intent to defraud in the course of Defendants' execution of the respective AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta Peer Selling, Publication, and DTC Enterprises.

1038. Defendants' respective false representations and omissions of material fact were false and were known to be false or known to have been asserted without knowledge of their truth by each Defendant.

1039. Each Defendant intended that, and Plaintiff and the Class Members did rely on each Defendant's false representations or omissions of material fact in purchasing, paying for, reimbursing, and making formulary placements of AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta. This reliance was at Plaintiff's and Class Members' detriment.

1040. Each Defendant's false representations or omissions of material fact made with the intent to defraud caused Plaintiff's and Class Members' injuries.

1041. Plaintiff and the Class Members were injured as a result of each Defendant's fraudulent representations or omissions, and are entitled to compensatory damages, exemplary

and/or punitive damages, to the extent allowable at law, costs and attorney's fees, as well as any other damages or relief allowable at law.

1042. Defendant's respective fraudulent conduct, set forth in detail above, constitutes actionable common law fraud under the laws of all fifty (50) states, the District of Columbia, and Puerto Rico.

1043. Plaintiff and the Class Members were injured as a proximate result of each Defendant's fraud, and are entitled to all damages allowable by law under the laws of each jurisdiction, costs and attorney's fees, and any other relief the Court deems necessary and appropriate.

THIRTY-SIXTH CLAIM FOR RELIEF
Negligent Misrepresentation (All Defendants)

1044. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

1045. Plaintiff and TPP Class Members are persons for whose benefit and guidance each Defendant supplied information concerning AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, with the intent that Plaintiff and TPP Class Members utilize that information in their business transactions and decisions concerning AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively.

1046. Each Defendant, in the course of its respective businesses, supplied and continues to supply false information for the guidance of TPP Plaintiff and the Class Members in their business transactions.

1047. Each Defendant intended that the false information supplied by each Defendant concerning AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, influence the business transaction decision-making of Plaintiff and TPP Class Members, as well

as other substantially similar transactions, or knew that Plaintiff and TPP Class Members intended to use said false information in business transactions.

1048. As detailed above, TPPs, through P&T Committees and PBMs, make formulary and reimbursement decisions regarding AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, relying extensively on information supplied directly and indirectly by Defendants.

1049. The information supplied by each Defendant concerning AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, and justifiably relied upon by Plaintiff and Class Members, was false, and each Defendant failed to exercise reasonable care or competence in obtaining or communicating the information to Plaintiff and the Class Members.

1050. Plaintiff and the Class Members suffered pecuniary loss proximately caused by each Defendant's negligent misrepresentations to Plaintiff and the Class Members concerning AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta.

1051. Defendants' negligent misrepresentations concerning AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, set forth in detail above, constitute actionable negligent misrepresentation under the laws of all fifty (50) states, the District of Columbia, and Puerto Rico.

1052. Plaintiff and the Class Members were injured as a proximate result of each Defendant's fraud, and are entitled to all damages allowable by law under the laws of each jurisdiction, costs and attorney's fees, and any other relief the Court deems necessary and appropriate.

THIRTY-SEVENTH CLAIM FOR RELIEF
Restitution/Disgorgement for Unjust Enrichment (All Defendants)

1053. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

1054. Defendants have been and continue to be enriched by their fraudulent acts and omissions alleged herein for all states wherein Class Members reside.

1055. In exchange for payments they made for AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, and at the time these payments were made, Plaintiff and the Class Members expected that the TRT drugs were safe and medically effective treatments for the condition, illness, disorder or symptoms for which they were prescribed.

1056. Defendants each voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiff and the Class Members paid for AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, when they otherwise would not have done so and paid for the drug at a higher price than would have been paid for but for Defendants' wrongful conduct.

1057. These fraudulent acts and omissions allow Defendants to gain billions of dollars in profits that would not have been gained but for Defendants' fraudulent acts and omissions

1058. Plaintiff and the Class Members and those similarly situated paid and continue to pay Defendants an amount that exceeds the value of the products identified herein as a result of Defendants' fraudulent acts and omissions.

1059. Plaintiff and the Class Members suffered damages due to Defendants' acts and omissions as alleged herein.

1060. Defendants have and continue to be unjustly enriched as a result of their fraudulent acts and omissions.

1061. Defendants lack any legal justification for engaging in a course of fraudulent acts and omissions as alleged herein at Plaintiff’s and the Class' expense.

1062. No other remedy at law can adequately compensate Plaintiff and the Class Members for the damages occasioned by Defendants' conscious choice to engage in a course of fraudulent acts and omissions.

1063. Plaintiff and the Class Members are entitled in equity to seek restitution of Defendants' wrongful profits, revenues and benefits concerning AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, to the extent and in the amount, deemed appropriate by the Court and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

THIRTY-EIGHTH CAUSE OF ACTION
Equitable Relief (All Defendants)

1064. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

1065. Each Defendant is under a legal duty imposed by the FDA to advise physicians of the latest changes in its labeling of AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively. Such communication, however, is limited to physicians. No notice is going to be provided to the proposed Class herein.

1066. Pursuant to the equitable relief provisions of RICO and applicable laws of the 50 states, Plaintiff seek temporary and/or permanent injunctive relief directing Defendants to notify in writing, and through other appropriate forms of notice, all members of the class as to the restrictions imposed on Defendants as to the limited indicated use of AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, as defined by the FDA.

1067. AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, have been heavily marketed to the medical community and the public. Not all prescribing physicians, nor all consumers of AndroGel, Testim and Testopel, Axiron, Androderm, and

Fortesta, respectively, will necessarily be aware of the action required of Defendants by the FDA. In order to ascertain that AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, is only being paid for or reimbursed by TPPs, it is imperative that TPPs also be advised as to the highly limited and restricted uses of AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, as mandated by the FDA.

1068. Such notice is necessary to enable TPPs prospectively to limit the payments or reimbursements of their covered lives only to those on-label uses of AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, as permitted by the FDA and to be aware of any off-label prescriptions. While physicians may be placed on notice as to the new label restrictions imposed on Defendants by the FDA, physicians are not the ones who bear the risk of loss for prescriptions beyond the bases approved by the FDA. TPPs pay the overwhelming majority of the cost for AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta prescriptions, respectively. Without such notice, TPPs will be unable to perform their obligation to only reimburse for prescription drugs within the various TPP plan provisions and protect themselves from incurring improper costs or charges in future.

1069. Without such notice, TPPs risk irreparable harm in paying or reimbursing for prescriptions of AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, beyond the limits set by the FDA. TPPs may not be able to fully recover monetary losses resulting from the payment or reimbursement for prescriptions of AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, beyond the on-label indications currently in force and effect.

1070. As Defendants are now limited in their marketing and promotion of AndroGel, Testim and Testopel, Axiron, Androderm, and Fortesta, respectively, pursuant to FDA

regulations and statutory authority, there should be no basis for opposition to advising TPPs in the same or similar fashion that they are notifying physicians of recent label changes mandated by the FDA.

1071. The equitable relief sought pursuant to RICO and the applicable laws of the 50 states is within the jurisdiction of this Honorable Court. The proposed notice class meets the requirements of FRCP 23(b)(2). Under this claim, Plaintiff seek no monetary damages on behalf of the proposed (b)(2) class. As noted herein, the proposed class meets the requirements of Rule 23. As such, equitable relief under Rule 23(b)(2) is appropriate and a (b)(2) class should be certified for the purposes of notice to TPPs as set forth herein.

XVI. DEMAND FOR RELIEF

WHEREFORE, Plaintiff and the Class Members demand judgment against Defendants, jointly and severally, as follows:

a) On Plaintiff's First, Second, Third, Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Tenth, Eleventh, Twelfth, Thirteenth, Fourteenth, Fifteenth, Sixteenth, Seventeenth, Eighteenth, Nineteenth, and Twentieth Claims for Relief, three times the damages each Plaintiff and Class Member has sustained as a result of each Defendant's conduct, plus Plaintiff's costs in this suit, including reasonable attorney fees;

b) On Plaintiff's Twenty-First, Twenty-Second, Twenty-Third, Twenty-Fourth, Twenty-Fifth, Twenty-Sixth, Twenty-Seventh, Twenty-Eighth, Twenty-Ninth, Thirtieth, Thirty-First, Thirty-Second, Thirty-Third, Thirty-Fourth, Thirty-Fifth, and Thirty-Sixth Claims for Relief, an award to each Plaintiff and Class Member of the maximum allowable damages under such statute(s) or laws;

c) On Plaintiff's Thirty-Seventh Claim for Relief, an award to each Plaintiff and Class Member of disgorgement of all sums improperly received by Defendants;

d) On Plaintiff's Thirty-Eighth Claim for Relief, all the equitable relief allowed;

e) An award of prejudgment interest in the maximum amount allowable by law;

f) An award to Plaintiff of their costs and expenses in this litigation and reasonable attorney fees and expert fees and expenses; and,

g) An award to Plaintiff and the Class Members of such other and further relief as may be just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demand a trial by jury on all issues so triable.

Dated this 5th day of November, 2014.

Respectfully submitted,

KANNER & WHITELEY, LLC
/s/ Conlee S. Whiteley
Allan Kanner, Esq. (LA Bar No. 20580)
Conlee S. Whiteley, Esq. (LA Bar No. 22678)
John R. Davis, Esq. (LA Bar No. 34872)
Luke A. Hasskamp, Esq. (CA Bar No. 280872)
701 Camp Street
New Orleans, Louisiana 70130
Tel: (504) 524-5777
Fax: (504) 524-5763

and

THE SIMMER LAW GROUP
W. Scott Simmer, Esq. (D.C. Bar No. 460726)
Thomas J. Poulin, Esq. (D.C. Bar No. 475115)
The Watergate
Suite 10-A
Washington, DC 20037
Tel: (202) 333-4562

Fax: (202) 337-1039

Attorneys for Plaintiff Medical Mutual of Ohio

SEEGER WEISS LLP
Stephen A. Weiss, Esq. (NY Bar No. 2413342)
Christopher A. Seeger, Esq. (NY Bar No. 2425304)
77 Water Street
New York, NY 10005
Tel: (212) 584-0700

SIMMONS HANLY CONROY
Trent B. Miracle, Esq. (IL Bar No. 6281491)
Brendan A. Smith, Esq. (IL Bar No. 65190)
One Court Street
Alton, IL 62002
Tel: (618) 259-2222
Fax: (618) 259-2251

and

SCHACHTER HENDY & JOHNSON PSC
Ronald E. Johnson, Jr., Esq. (KY Bar No. 88302)
Sarah N. Lynch, Esq. (KY Bar No. 94261)
909 Wright's Summit Parkway
Suite #210
Ft. Wright, KY 41011
Tel: (859) 578-4444
Fax: (859) 578-4440

MDL Co-Lead Counsel