BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: ANDROGEL PRODUCTS LIABILITY LITIGATION	:	**MDL DOCKET NO. 2545**

OPPOSITION OF AUXILIUM PHARMACEUTICALS, INC. TO MOTIONS FOR TRANSFER AND CONSOLIDATION UNDER 28 U.S.C. § 1407 OF ALL TESTOSTERONE REPLACEMENT THERAPY ACTIONS INTO ONE MDL

I. INTRODUCTION

Auxilium Pharmaceuticals, Inc. ("Auxilium") is a biopharmaceutical company located in Pennsylvania. Auxilium has an exclusive license to manufacture and distribute an FDA-approved Testosterone Replacement Therapy ("TRT") medication called Testim®, and it also sells another other FDA-approved TRT drug, Testopel®. At this time, Auxilium opposes the motions and requests for transfer filed with the Joint Panel on Multidistrict Litigation (the "Panel") insofar as they seek coordinated pretrial proceeding of all cases against all manufacturers of TRT drugs.

To date, only seven federal cases have been filed against Auxilium (three of which name Auxilium as the sole defendant). Although Auxilium does not oppose an AndroGel® MDL, it opposes an industry-wide MDL given the small number of cases pending against Auxilium. Even though all TRT cases would involve some abstract common questions, individualized issues about plaintiffs, defendants, and physicians will be more significant to liability.

Six of the seven federal lawsuits against Auxilium involve Testim® and one involves Testopel®. Auxilium is the sole defendant in three cases, and a co-defendant with AbbVie, Inc. ("AbbVie") and Abbott Laboratories, Inc. ("Abbott") in four others (one of which also includes Pfizer, Inc. ("Pfizer"), and another of which also includes Eli Lilly and Company and Lilly USA,

LLC (collectively, "Eli Lilly")).[1] Auxilium recognizes that the cases against Abbott and AbbVie (including the cases in which Auxilium is a defendant) are likely to be transferred to a single venue for coordinated pretrial proceedings. Auxilium agrees with AbbVie, Abbott, Eli Lilly, and Endo Pharmaceuticals that the Northern District of Illinois is the proper venue for any such MDL.[2]

II. PROCEDURAL BACKGROUND

A. Requests for Transfer and Consolidation

There have been six requests for creation of a MDL filed with the Panel involving a total of 71 cases. The initial motion to transfer was filed on March 28, 2014 by plaintiffs in cases filed in the Northern District of Illinois against AbbVie and Abbott relating to AbbVie's AndroGel® medication (the "Illinois Plaintiffs"). (Dkt. No. 1.) The Illinois Plaintiffs request that the Panel create a MDL of all cases related to AndroGel®, consolidated in the Northern District of Illinois before Judge Kennelly. (Dkt. No. 1 at 1-4.) Since that time, a number of additional motions or responses have been filed by plaintiffs requesting that the Panel create a MDL that includes ***all*** TRT manufacturers and their medicines, and requesting that the MDL be located in the Eastern District of Pennsylvania (Dkt. Nos. 25 & 37), the Eastern District of Louisiana (Dkt. Nos. 17, 60 & 79), or the District of Colorado (Dkt. No. 61).

B. Only Seven Federal Cases Have Been Filed Against Auxilium

Seven cases have been filed against Auxilium in three U.S. District Courts. *See* List of Associated Actions, attached as Exhibit A. There are three cases pending in the Eastern District

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[1] Auxilium is also a defendant in six cases pending in the Pennsylvania Court of Common Pleas, Philadelphia County, related to Testim®. Some of these cases are brought jointly against Auxilium and GlaxoSmithKline, LLC, who agreed to co-promote Testim® to physicians between May 2012 and August 2013.

[2] Even if the Panel were to create an industry-wide MDL, Auxilium believes the Northern District of Illinois would be the proper forum for the reasons identified by those Defendants.

of Pennsylvania, three in the Eastern District of Louisiana, and one in the Northern District of Illinois. Six of those cases involve Testim® and one involves Testopel®. Auxilium is a co-defendant with AbbVie and Abbott in four of the cases (and a co-defendant with Pfizer and with Eli Lilly, respectively, in one each of those four cases). Auxilium is named as the sole defendant in three cases. There are no allegations that Auxilium acted in concert with or is otherwise jointly and severally liable with any of the other manufacturers.

Plaintiffs in the TRT cases generally attempt to allege that they began taking testosterone therapy after seeing marketing literature, but that such materials allegedly failed to adequately advise consumers and physicians of alleged cardiovascular and/or cerebrovascular risks of such therapies. Based on these allegations, the complaints typically include a variety of claims under state law – strict product liability and negligence claims based on failure to warn and design defect theories, as well as claims for breach of express and implied warranties, fraud, and negligent misrepresentation.

III. LEGAL ARGUMENTS

A. Legal Standard

Under 28 U.S.C. § 1407(a), the Panel can order transfer where actions pending in different districts "involv[e] one or more common questions of fact." Although the Panel has the power to do so, there is little reason to transfer cases held together by common questions that are not central to the parties' dispute or which otherwise will not consume a significant amount of time relative to the litigations as a whole. *See, e.g.*, *In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010) (denying transfer despite some common factual allegations because "individual issues of causation and liability continue to appear to predominate, and remain likely to overwhelm any efficiencies that might be gained by

centralization"). Differences among manufacturer defendants and products here weigh against including the cases involving only Auxilium in any multi-district proceeding.

The Panel also examines whether transfer will be convenient for the "parties and witnesses and will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). There is no presumption in favor of transfer under section 1407, and the Panel has noted that centralization "should be the last solution after considered review of all other options." *In re Best Buy Co. Inc., California Song-Beverly Credit Card Act Litig.*, MDL Nos. 2256, 2259, 2260, 2267, 2268, 804 F. Supp. 2d 1376, 1378 (J.P.M.L. 2011).

In exercising its discretion, the Panel weighs several practical considerations. For example, transfer has been denied where there are few actions and the use of existing pretrial mechanisms would eliminate the possibility of duplicative and inconvenient discovery. *See In re Eli Lilly & Co. Patent Litig.*, 446 F. Supp. 242, 244 (J.P.M.L. 1978); *see also* Manual for Complex Litig. § 20.14 (4th ed. 2004) (noting that litigants in related cases can request assignment to one judge within a district as well as cross-file deposition notices, interrogatories, and requests for production across districts). The Panel has also denied transfer where the number of actions and counsel involved were relatively limited. *See, e.g.*, *In re Trilegiant Membership Program Mktg. & Sales Pracs. Litig.*, 828 F. Supp. 2d 1362, 1363 (J.P.M.L. 2011) (denying transfer involving six actions, noting that "[t]he relatively few involved counsel also weighs against centralization, and should facilitate informal coordination and cooperation across the actions"). These factors (and others) weigh against transfer and centralization of the three cases involving only Auxilium.

B. The Panel Should Not Create A MDL Covering All TRT Manufacturers Where Some Manufacturers Oppose A MDL Because They Are Not Yet Involved In A Significant Number Of Cases.

The Panel has discretion to order transfer and centralization only if, among other factors, it "will be for the convenience of the parties." 28 U.S.C. § 1407(a). This factor weighs against industry-wide transfer and centralization where, as here, some parties oppose it. *See, e.g.*, *In re Property Assessed Clean Energy (PACE) Programs Litig.*, 764 F. Supp. 2d 1345, 1347 (J.P.M.L. 2011) (denying centralization because, among other factors, "the bulk of the parties" opposed centralization).

Here, Auxilium and Actavis oppose creation of an industry-wide MDL of all TRT manufacturers because neither manufacturer is involved in more than a handful of federal cases. In light of this opposition, and the fact that movants have not demonstrated that an industry-wide MDL is convenient for all parties, the Panel should exercise its discretion to reject an industry-wide MDL at this time. The Panel may instead consider creating an AndroGel®-only MDL, given that AbbVie and Abbott do not oppose a MDL, and that the vast majority of actions involve AbbVie and Abbott as the only defendants, compared to a small number of cases against the other defendants that are far too few, standing alone, to justify MDL treatment for their products at this time. (*See* Certificate of Service filed herewith, which, as of the date of filing, lists all related actions and shows that 56 out of the 71 total related actions are brought against AbbVie and Abbott only regarding Androgel® only); *see also In re Yellow Brass Plumbing Component Prods. Liab. Litig.*, 844 F. Supp. 2d 1377, 1378-79 (J.P.M.L. 2012) (denying industry-wide centralization because "we are typically hesitant to centralize litigation against multiple, competing defendants which marketed, manufactured and sold similar products. . . . [W]e are not persuaded that centralization of these actions would serve the convenience of the parties and witnesses or further the just and efficient conduct of this litigation.").

Accordingly, movants' request for an industry-wide TRT MDL should be denied as such a MDL is opposed by two defendants and, in any event, the number of actions now pending against these defendants opposing a MDL would not support MDL treatment for their products.

C. Although Abstract Common Questions Exist, They Are Not Significant To Determining Liability In Any Particular Case.

Although there may be an abstract common issue regarding general causation, *i.e.*, whether testosterone might present cardiac and cerebral risks, specific and individualized facts regarding plaintiffs, defendants, and physicians will be more significant to any finding of liability. Because of the narrow band of common questions of fact and the limited number of non-Abbott and non-AbbVie cases, the efficiency gains at this time will be limited such that the Panel should decline the invitation to create a MDL involving all TRT manufacturers. *See In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d at 1377 (denying request for consolidation because individual questions about different products in "different sizes and designs, with differing" characteristics and plaintiffs with different medical histories predominated over common factual issues).

- First, the cases involve several different manufacturers (at least ten) and at least several different TRT medications (at least six).[3] The medications at issue come from different manufacturers, are sold in different formulations, are applied in different ways, and – critically important given plaintiffs' allegations – have unique promotional and FDA-approval histories.[4] Here, the several TRT drugs on the market come in different strengths and different formulations and delivery methods.

[3] Although some plaintiffs assert that nine cases involve drugs in addition to AndroGel®, as of this date only the following six products have been identified in the related actions currently before the Panel: AndroGel®, AndroDerm®, Axiron®, Depo-Testosterone®, Fortesta®, and Testim®. (*See* Dkt. No. 17-1 at 1.)

[4] For example, Auxilium's products are applied in different ways. Testim® is a topical gel that is applied each morning to the shoulders and upper arms. *See* Testim® FDA-approved Full Prescribing Information (attached as Exhibit B). Testopel® is a pellet treatment that is placed under the skin by a physician to deliver testosterone over a longer period of time. *See* Testopel® FDA-approved Full Prescribing Information (attached as Exhibit C). There are differences

- Second, plaintiffs acknowledge that TRT manufacturers used different marketing campaigns directed to consumers that were purportedly designed to convince them that symptoms associated with normal aging were actually attributable to "Low-T." Plaintiffs in the TRT cases do not allege that Auxilium or any of the other TRT manufacturers advertised their products together, or in any way collaborated in the marketing and promotion of TRT medications. Instead, the manufacturers are competitors, each with its own promotional materials utilizing different media outlets, such as print, radio, television, or internet. And, not all manufacturers advertised through all of these forums. Each manufacturer's advertising and marketing is unique to that defendant.

- Third, for each case, the knowledge and prescribing decision(s) of each plaintiff's prescribing doctor will be critical. Applicable state laws generally provide that the duty to warn of risks associated with prescription medications runs not to the patient, but to the doctor who has sole prescribing authority.[5] Therefore, in each case it will be essential to discover the "who, what, when, where, and why" of the informational and promotional materials about Testim® and/or other TRT products that plaintiffs' doctors read and relied on.

- Fourth, plaintiffs allege that published studies establish an association between TRT products and increased levels of hematocrit, hemoglobin, and/or estradiol in the body that, in turn, increase risks of cardiac injury and stroke. The medical causation issues will necessarily be different for each plaintiff and potentially implicate differences between the various testosterone medicines.

The Panel has previously denied consolidation in cases involving different prescription products manufactured by different companies and used by different plaintiffs. For example, in *In re Shoulder Pain Pump-Chondrolysis Prods. Liab. Litig.*, 571 F. Supp. 2d 1367, 1368 (J.P.M.L. 2008), although the Panel found that the cases had "some commonality as to whether shoulder pain pumps and/or the anesthetic drugs used in those pumps cause glenohumeral

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among other TRT medications as well, *e.g.*, Delatestryl® and Depo-Testosterone® are injected by a doctor every two weeks. *See* Delatestryl®, *available at* http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=67e2cc36-a379-11dc-8314-0800200c9a66 (last visited April 25, 2014); Depo-Testosterone®, *available at* http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=cfbb53d4-b868-4a28-8436-f9112eb01c39 (last visited April 25, 2014).

[5] *See generally Bergstresser v. Bristol-Myers Squibb Co.*, No. 3:12-1464, 2013 WL 1760525, at *5 (M.D. Pa. Apr. 24, 2013) ("Where a case involves a negligent failure-to-warn regarding a pharmaceutical drug, the Pennsylvania courts have adopted the 'learned intermediary doctrine.'") (citation omitted).

chondrolysis," it denied transfer because they involved different drugs made by different pharmaceutical companies, many of whom were sued in "only a minority" of the actions. *See In re Watson Fentanyl Patch Prods. Liab. Litig.*, MDL 2372, 883 F. Supp. 2d 1350, 1351 (J.P.M.L. 2012) (refusing to include different products within a Watson-specific fentanyl patch MDL because "[e]ach group of cases against each manufacturer will involve unique product—and defendant-specific issues (such as the different product designs, manufacturing processes, regulatory histories, and company documents and witnesses) that will overwhelm the few common issues."); *see also In re Pfizer Inc. Mktg. & Sales Practices Litig.*, 657 F. Supp. 2d 1367, 1368 (J.P.M.L. 2009) (refusing to centralize two actions into an MDL that involved eleven different prescription drugs because the Panel was not convinced "at the present time" that centralization under Section 1407 would serve the convenience of the parties and witnesses or further the just and efficient conduct of the litigation).

Given the limited number of TRT actions that involve products other than AndroGel®, it is not apparent at this time that an all-TRT MDL would share common significant and complex issues related to any liability determinations such that it would be efficient for all involved. *See, e.g.*, *In re Nutella Mktg. & Sales Practices Litig.*, MDL 2248, 804 F. Supp. 2d 1374, 1375 (J.P.M.L. 2011) (denying unopposed motion for consolidation of two actions where the Panel was not convinced "that any common factual questions are sufficiently complex or numerous to justify Section 1407 transfer at this time"); *In re Prof'l Basketball Antitrust Litig.*, 344 F. Supp. 1405, 1406-07 (J.P.M.L. 1972) (denying transfer as "premature at this time" and denying the motion "without prejudice to the right of the parties to seek transfer at a later time" where movants did not convince the Panel as to the "existence of questions of fact common to these cases"). If additional TRT actions are filed against manufacturers of TRT medications other than

AndroGel®, the parties may return with a renewed request for an all-TRT MDL based upon a more developed record that would allow this Panel to more appropriately assess whether common factual issues warrant centralization. *E.g.*, *In re Am. Home Realty Network, Inc., Multiple Listing Serv. Copyright Infringement Litig.*, MDL 2431, 939 F. Supp. 2d 1372, 1373 (J.P.M.L. 2013) (denying transfer and noting that "[i]n the event that additional related actions are filed . . . the parties may file another Section 1407 motion, and the Panel may revisit the question of centralization at that time"). Thus, the Panel should decline the invitation to create an industry-wide MDL at this time.

CONCLUSION

For the foregoing reasons, the Panel should deny the requests for an industry-wide MDL at the present time.

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Respectfully submitted,

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BEFORE THE
UNITED STATES JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

IN RE: ANDROGEL PRODUCT LIABILITY LITIGATION	§ § § § § §	MDL DOCKET NO. 2545

LIST OF ASSOCIATED CASES

1. *Barrios v. AbbVie, Inc., et al.*, U. S. District Court, Eastern District of Louisiana, Civil Action No. 2:14-cv-00839-MLCF-DEK

2. *Peuler v. Auxilium Pharmaceuticals, Inc.*, U. S. District Court, Eastern District of Louisiana, Civil Action No. 2:14-cv-00658

3. *Parker v. AbbVie, Inc., et al.*, U. S. District Court, Northern District of Illinois, Eastern Division, Civil Action No. 1:14-cv-02394

4. *Hill v. Auxilium Pharmaceuticals, Inc.*, U. S. District Court, Eastern District of Pennsylvania, Civil Action No. 2:14-cv-2189

5. *Amerson v. Abbott Laboratories, Inc., et al.*, U. S. District Court, Eastern District of Pennsylvania, Civil Action No. 2:14-cv-2206

6. **Simpson v. Auxilium Pharmaceucticals, Inc.*, U. S. District Court, Eastern District of Louisiana, Civil Action No. 2:14-cv-00927

7. **Oxsheer v. Abbott Laboratories, Inc., et al.*, U. S. District Court, Eastern District of Pennsylvania, Civil Action No. 2:14-cv-2391

* These cases have been filed in federal court and relate to TRT medications but, to date, have not been noticed to the Panel as a related case.

EXHIBIT B

Testim® 1% (testosterone gel) CIII

WARNING: SECONDARY EXPOSURE TO TESTOSTERONE

- **Virilization has been reported in children who were secondarily exposed to testosterone gel.**
- **Children should avoid contact with unwashed or unclothed application sites in men using testosterone gel.**
- **Healthcare providers should advise patients to strictly adhere to recommended instructions for use.**

(See WARNINGS, Potential for Secondary Exposure to Testosterone)

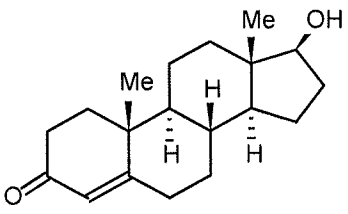
DESCRIPTION

Testim® (testosterone gel) is a clear to translucent hydroalcoholic topical gel containing 1% testosterone. Testim® provides continuous transdermal delivery of testosterone for 24 hours, following a single application to intact, clean, dry skin of the shoulders and upper arms.

One 5 g or two 5 g tubes of Testim® contains 50 mg or 100 mg of testosterone, respectively, to be applied daily to the skin's surface. Approximately 10% of the applied testosterone dose is absorbed across skin of average permeability during a 24-hour period.

The active pharmacological ingredient in Testim® is testosterone.

Testosterone ($C_{19}H_{28}O_2$) MW: 288.42



Testosterone

Testosterone USP is a white to practically white crystalline powder chemically described as 17-β hydroxyandrost-4-en-3-one. Inactive ingredients in Testim® are purified water, pentadecalactone, carbopol, acrylates, propylene glycol, glycerin, polyethylene glycol, ethanol (74%), and tromethamine.

CLINICAL PHARMACOLOGY

Testim® 1% (testosterone gel) delivers physiologic amounts of testosterone, producing circulating testosterone levels that approximate normal levels (e.g., 300 – 1000 ng/dL) seen in healthy men.

Testosterone – General Androgen Effects:

Testosterone and dihydrotestosterone (DHT), endogenous androgens, are responsible for normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. These effects include the growth and maturation of the prostate, seminal vesicles, penis, and scrotum; the development of male hair distribution, such as facial, pubic, chest, and axillary hair; laryngeal enlargement; vocal cord thickening; alterations in body musculature; and fat distribution.

Male hypogonadism results from insufficient secretion of testosterone and is characterized by low serum testosterone concentrations. Symptoms associated with male hypogonadism include decreased sexual desire with or without impotence, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics, and osteoporosis. Hypogonadism is a risk factor for osteoporosis in men.

Drugs in the androgen class also promote retention of nitrogen, sodium, potassium, phosphorus, and decreased urinary excretion of calcium.

Androgens have been reported to increase protein anabolism and decrease protein catabolism. Nitrogen balance is improved only when there is sufficient intake of calories and protein. Androgens have been reported to stimulate the production of red blood cells by enhancing erythropoietin production.

Androgens are responsible for the growth spurt of adolescence and for the eventual termination of linear growth brought about by fusion of the epiphyseal growth centers. In children, exogenous androgens accelerate linear growth rates but may cause a disproportionate advancement in bone maturation. Use over long periods may result in fusion of the epiphyseal growth centers and termination of the growth process.

During exogenous administration of androgens, endogenous testosterone release may be inhibited through feedback inhibition of pituitary luteinizing hormone (LH). At large doses of exogenous androgens, spermatogenesis may also be suppressed through feedback inhibition of pituitary follicle-stimulating hormone (FSH).

There is a lack of substantial evidence that androgens are effective in accelerating fracture healing or in shortening post-surgical convalescence.

Pharmacokinetics

The pharmacokinetics of Testim® have been evaluated with administration of doses containing 50 mg and 100 mg of testosterone to adult males with morning testosterone levels ≤300 ng/dL.

Absorption

Testim® is a topical formulation that dries quickly when applied to the skin surface. The skin serves as a reservoir for the sustained release of testosterone into the systemic circulation. Approximately 10% of the testosterone applied on the skin surface is absorbed into the systemic circulation during a 24-hour period.

Single Dose

In single dose studies, when either Testim® 50 mg or 100 mg was administered, absorption of testosterone into the blood continued for the entire 24 hour dosing period. Also, mean peak and average serum concentrations within the normal range were achieved within 24 hours.

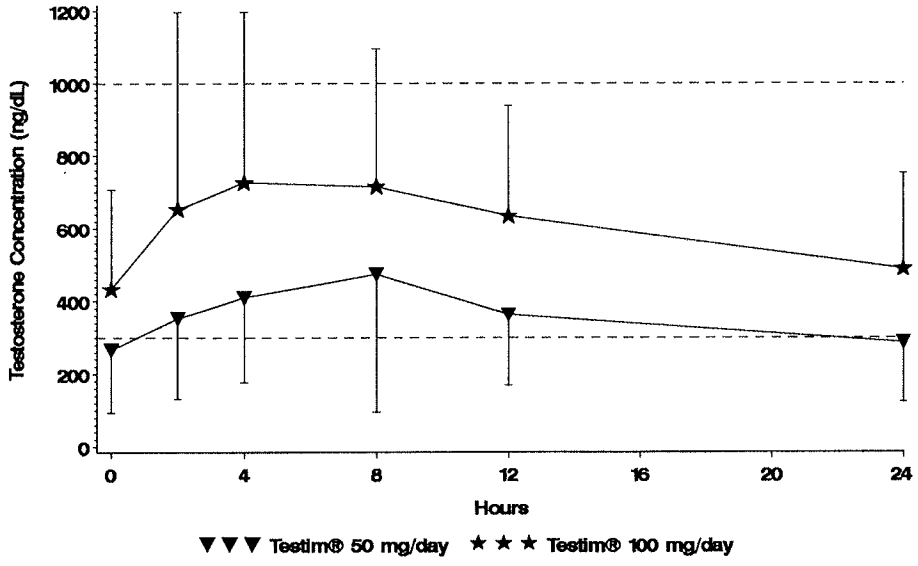
Multiple Dose

With single daily applications of Testim® 50 mg and 100 mg, follow-up measurements at 30 and 90 days after starting treatment have confirmed that serum testosterone and DHT concentrations are generally maintained within the normal range.

Figure 1 summarizes the 24-hour pharmacokinetic profile of testosterone for patients maintained on Testim® 50 mg or Testim® 100 mg for 30 days.

Figure 1

Mean Steady-State Serum Testosterone (±SD) (ng/dL) Concentrations on Day 30 in Patients Applying Testim® Once Daily

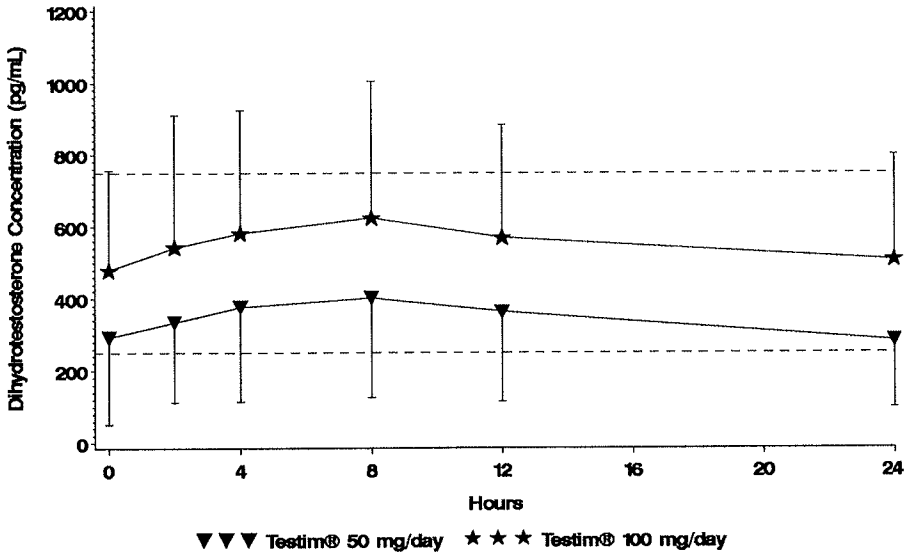


The average daily testosterone concentration produced by Testim® 100 mg at Day 30 was 612 (± 286) ng/dL and by Testim® 50 mg at Day 30 was 365 (± 187) ng/dL.

Figure 2 summarizes the 24-hour pharmacokinetic profile of DHT for patients maintained on Testim® 50 mg or Testim® 100 mg for 30 days.

Figure 2

Mean Steady-State Serum Dihydrotestosterone (±SD) (pg/mL) Concentrations on Day 30 in Patients Applying Testim® Once Daily



The average daily DHT concentration produced by Testim® 100 mg at Day 30 was 555 (± 293) pg/mL and by Testim® 50 mg at Day 30 was 346 (± 212) pg/mL.

Washing

The effect of showering (with mild soap) at 1, 2 and 6 hours post application of Testim® 100 mg was evaluated in a clinical trial in 12 men. The study demonstrated that the overall effect of washing was to lessen testosterone levels; however, when washing occurred two or more hours post drug application, serum testosterone levels remained within the normal range.

Distribution

Circulating testosterone is chiefly bound in the serum to sex hormone-binding globulin (SHBG) and albumin. The albumin-bound fraction of testosterone easily dissociates from albumin and is presumed to be bioactive. The portion of testosterone bound to SHBG is not considered biologically active. Approximately 40% of testosterone in plasma is bound to SHBG, 2% remains unbound (free) and the rest is bound to albumin and other proteins. The amount of SHBG in the serum and the total testosterone level will determine the distribution of bioactive and nonbioactive androgen.

Metabolism

There is considerable variation in the half-life of testosterone as reported in the literature, ranging from ten to 100 minutes.

Testosterone is metabolized to various 17-keto steroids through two different pathways. The major active metabolites of testosterone are estradiol and DHT. Testosterone is metabolized to DHT by steroid 5α-reductase located in the skin, liver, and the urogenital tract of the male. DHT binds with greater affinity to SHBG than does testosterone. In many tissues, the activity of testosterone depends on its reduction to DHT, which binds to cytosol receptor proteins. The steroid-receptor complex is transported to the nucleus where it initiates transcription and cellular changes related to androgen action. In reproductive tissues, DHT is further metabolized to 3α and 3β androstanediol. Inactivation of testosterone occurs primarily in the liver.

DHT concentrations increased in parallel with testosterone concentrations during Testim® treatment. After 90 days of treatment, mean DHT concentrations remained generally within the normal range for Testim®-treated subjects.

Excretion

About 90% of a testosterone dose given intramuscularly is excreted in the urine as glucuronic and sulfuric acid conjugates of testosterone and metabolites; about 6% of a dose is excreted in the feces, mostly in the unconjugated form.

Special Population

In patients treated with Testim® there are no observed differences in the average daily serum testosterone concentration at steady-state based on age or cause of hypogonadism. No formal studies were conducted in a pediatric age population or in patients with renal or hepatic insufficiencies.

Clinical Studies

Testim® was evaluated in a randomized multicenter, multi-dose, active and placebo controlled 90-day study in 406 adult males with morning testosterone levels ≤300 ng/dL. The study was double-blind for the doses of Testim® and placebo, but open label for the non-scrotal testosterone transdermal system. During the first 60 days, patients were evenly randomized to Testim® 50 mg, Testim® 100 mg, placebo gel, or testosterone transdermal system. At Day 60, patients receiving Testim® were maintained at the same dose, or were titrated up or down within their treatment group, based on 24-hour averaged serum testosterone concentration levels obtained on Day 30.

Of 192 hypogonadal men who were appropriately titrated with Testim® and who had sufficient data for analysis, 74% achieved an average serum testosterone level within the normal range on treatment Day 90.

Table 1 summarizes the mean testosterone concentrations on Day 30 for patients receiving Testim® 50 mg or 100 mg.

Table 1: Mean (± SD) Steady-State Serum Testosterone Concentrations on Day 30

	Testim® 50 mg n=94	**Testim® 100 mg n=95**	**Placebo n=93**
C_{avg} (ng/dL)	365 ± 187	612 ± 286	216 ± 79
C_{max} (ng/dL)	538 ± 371	897 ± 565	271 ± 110
C_{min} (ng/dL)	223 ± 126	394 ±189	164 ± 64

At Day 30, patients receiving Testim® 100 mg daily showed significant improvement from baseline in multiple sexual function parameters as measured by patient questionnaires when compared to placebo. These parameters included sexual motivation, sexual desire, sexual activity and spontaneous erections. For Testim® 100 mg, improvements in sexual motivation, spontaneous erections, and sexual desire were maintained through Day 90. Sexual enjoyment and satisfaction with erection duration were improved compared to baseline but these improvements were not significant compared to the placebo group.

In Testim®-treated patients, the number of days in which sexual activity was reported to occur increased by 123% from baseline at Day 30 and was still increased from baseline by 59% at Day 90. The number of days with spontaneous erections increased by 137% at Day 30 and was maintained at 78% at Day 90 for Testim®-treated patients compared to baseline.

Table 2 summarizes the changes in body composition at Day 90 for patients receiving Testim® 50 mg or 100 mg as measured by standardized whole body DEXA (Dual Energy X-ray Absorptiometry) scanning.

Table 2: Effect of Testim® on Lean Body Mass, Total Fat Mass and % Body Fat

Days of Treatment	Lean Body Mass (Muscle) (kg)	Total Fat Mass (kg)	% Body Fat
Baseline	61.6	29.4	30.9
Day 90	63.3	28.6	29.8
Change from Baseline	↑1.6	↓0.8	↓1.1

At Day 90, mean increases from baseline in lean body mass and mean decreases from baseline in total fat mass and percent body fat in Testim®-treated patients were significant when compared to placebo-treated patients.

Potential for Testosterone Transfer

The potential for dermal testosterone transfer following Testim® use was evaluated in two clinical trials with males dosed with Testim® and their untreated female partners.

In the first trial (AUX-TG-206), 30 couples were evenly randomized to five groups. In the first four groups, 100 mg of Testim® was applied to the male abdomen and the couples were then asked to rub abdomen-to-abdomen for 15 minutes at 1 hour, 4 hours, 8 hours or 12 hours after dose application, respectively. In these couples, serum testosterone concentrations in female partners increased from baseline by at least 4 times and potential for transfer was seen at all timepoints.

When 6 males used a shirt to cover the abdomen at 15 minutes post-application and partners again rubbed abdomens for 15 minutes at the 1 hour timepoint, the potential for transfer was markedly reduced.

In the second trial (AUX-TG-209), 24 couples were evenly randomized to four groups. Testim® 100 mg was applied to the male arms and shoulders. In one group, 15 minutes of direct skin-to-skin rubbing began at 4 hours after application. In these six women, all of whom showered immediately after the rubbing activity, mean maximum serum testosterone concentrations increased from baseline by approximately 4 times. When males wore a long-sleeved T-shirt and

rubbing was started at 1 and at 4 hours after application, the transfer of testosterone from male to female partners was prevented.

INDICATIONS AND USAGE

Testim® is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

1. Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and gonadotropins (FSH, LH) above the normal range.
2. Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in the normal or low range.

Testim® has not been clinically evaluated in males under 18 years of age.

CONTRAINDICATIONS

Androgens are contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate. Testim® is not indicated for use in women, has not been evaluated for use in women, and must not be used in women.

Pregnant and nursing women should avoid skin contact with Testim® application sites on men. Testosterone may cause fetal harm. Testosterone exposure during pregnancy has been reported to be associated with fetal abnormalities. In the event that unwashed or unclothed skin to which Testim® has been applied comes in direct contact with the skin of a pregnant or nursing woman, the general area of contact on the woman should be immediately washed with soap and water.

Testim® should not be used in patients with known hypersensitivity to any of its ingredients, including testosterone USP that is chemically synthesized from soy.

WARNINGS

1. Men with benign prostatic hyperplasia (BPH) are at an increased risk for worsening of BPH. In addition, men treated with androgens may be at an increased risk for prostate cancer. Geriatric patients and other patients with clinical or demographic characteristics that are recognized to be associated with an increased risk of prostate cancer should be evaluated for the presence of prostate cancer prior to initiation of testosterone replacement therapy. In men receiving testosterone replacement therapy, surveillance for prostate cancer should be consistent with current practices for eugonadal men (see PRECAUTIONS, Carcinogenesis, Mutagenesis, Impairment of Fertility and Laboratory Tests).

2. Potential for Secondary Exposure to Testosterone
   - Secondary exposure to testosterone in children and women can occur with testosterone gel use in men. Cases of secondary exposure resulting in virilization of children have been reported in postmarketing surveillance of testosterone-containing gel products. Signs and symptoms have included enlargement of the penis or clitoris, development of pubic hair, increased erections and libido, aggressive behavior, and advanced bone age. In most cases, these signs and symptoms regressed with removal of the exposure to testosterone. In a few cases, however, enlarged genitalia did not fully return to age-appropriate normal size, and bone age remained modestly greater than chronological age. The risk of transfer was increased in some of these cases by not adhering to precautions for the appropriate use of the testosterone gel product.

   - Inappropriate changes in genital size or development of pubic hair or libido in children, or changes in body hair distribution, significant increase in acne, or other signs of virilization in adult women should be brought to the attention of a physician, and the possibility of secondary exposure to testosterone gel should also be brought to the

attention of a physician. Testosterone gel should be promptly discontinued until the cause of virilization has been identified.

3. **Strict adherence to the following precautions is advised in order to minimize the potential for secondary exposure to testosterone from Testim®-treated skin:**

   - Children and women should avoid contact with Testim® application sites on the skin of men using Testim.
   - Testim® should only be applied to the shoulders or upper arms (area of application should be limited to the area that will be covered by the patient's short sleeve t-shirt).
   - Patients should wash their hands thoroughly and immediately with soap and water after application of Testim®.
   - Patients should cover the application site(s) with clothing (e.g., a shirt) after the gel has dried.
   - Prior to any situation in which skin-to-skin contact is anticipated, patients should wash the application site(s) thoroughly with soap and water to remove any testosterone residue.
   - In the event that unwashed or unclothed skin to which Testim® has been applied comes in direct contact with the skin of another person, the general area of contact on the other person should be washed with soap and water as soon as possible. Studies show that residual testosterone is removed from the skin surface by washing with soap and water.

4. Testim® should not be applied to the abdomen.

5. Prolonged use of high doses of orally active 17-alpha-alkyl androgens (e.g., methyltestosterone) has been associated with serious hepatic adverse effects (peliosis hepatis, hepatic neoplasms, cholestatic hepatitis, and jaundice). Peliosis hepatis can be a life-threatening or fatal complication. Long-term therapy with testosterone enanthate, which

elevates blood levels for prolonged periods has produced multiple hepatic adenomas. Transdermal testosterone is not known to produce these adverse effects.

6. Edema, with or without congestive heart failure, may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required.

7. Gynecomastia occasionally develops and occasionally persists in patients being treated for hypogonadism.

8. The treatment of hypogonadal men with testosterone may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung diseases.

PRECAUTIONS

General

The physician should instruct patients to report any of the following:

- Too frequent or persistent erections of the penis.
- Any changes in skin color, ankle swelling or unexplained nausea and vomiting.
- Breathing disturbances, including those associated with sleep.

Information for Patients

Advise patients to carefully read the Medication Guide that accompanies each carton of Testim® single-use tubes.

Advise Patients of the Following:

1. Men with known or suspected prostate or breast cancer should not use Testim®.

2. Secondary exposure to testosterone in children and women can occur with the use of testosterone gel products in men. Cases of secondary exposure to testosterone have been reported in children with signs and symptoms including enlargement of the penis or clitoris, premature development of pubic hair, increased erections, and aggressive behavior.

   Unexpected sexual development including inappropriate enlargement of the penis or clitoris, premature development of pubic hair, increased erections, and aggressive behavior in children, or changes in hair distribution, increase in acne, or other signs of testosterone effects in adult women should be brought to the attention of a physician and the possibility of secondary exposure to testosterone gel also should be brought to the attention of a physician. Testosterone gel should be promptly discontinued until the cause of virilization is identified.

3. **Strict adherence to the following precautions is advised in order to minimize the potential for secondary exposure to testosterone from Testim®-treated skin:**

   - Children and women should avoid contact with Testim® application sites on the skin of men using Testim®.
   - Testim® should only be applied to the shoulders or upper arms (area of application should be limited to the area that will be covered by the patient's short sleeve t-shirt).
   - Patients should wash their hands thoroughly and immediately with soap and water after application of Testim®.
   - Patients should cover the application site(s) with clothing (e.g., a shirt) after the gel has dried.
   - Prior to any situation in which skin-to-skin contact is anticipated, patients should wash the application site(s) thoroughly with soap and water to remove any testosterone residue.

- In the event that unwashed or unclothed skin to which testosterone gel has been applied comes in direct contact with the skin of another person, the general area of contact on the other person should be washed with soap and water as soon as possible. Studies show that residual testosterone is removed from the skin surface by washing with soap and water.

Also advise patients of the following:

- Testim® should not be applied to the scrotum, penis, or abdomen.

- Testim® should be applied once daily at approximately the same time each day to clean dry skin of the shoulders and/or upper arms.

- Washing or swimming may lessen testosterone levels; however, when washing occurs two or more hours post drug application, serum testosterone levels remain within the normal range.

Laboratory Tests

1. Hemoglobin and hematocrit levels should be checked periodically (to detect polycythemia) in patients on long-term androgen therapy.
2. Liver function, prostate specific antigen (PSA), cholesterol, and high-density lipoprotein (HDL) should be checked periodically.
3. To ensure proper dosing, serum testosterone concentrations should be measured (see DOSAGE AND ADMINISTRATION).

Drug Interactions

Oxyphenbutazone: Concurrent administration of oxyphenbutazone and androgens may result in elevated serum levels of oxyphenbutazone.

Insulin: In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, insulin requirements.

Propranolol: In a published pharmacokinetic study of an injectable testosterone product, administration of testosterone cypionate led to an increased clearance of propranolol in the majority of men tested. It is unknown if this would apply to Testim®.

Corticosteroids: The concurrent administration of testosterone with ACTH or corticosteroids may enhance edema formation; thus these drugs should be administered cautiously, particularly in patients with cardiac or hepatic disease.

Drug/Laboratory Test Interactions

Androgens may decrease levels of thyroxin-binding globulin, resulting in decreased total T4 serum levels and increased resin uptake of T3 and T4. Free thyroid hormone levels remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal Data: Testosterone has been tested by subcutaneous injection and implantation in mice and rats. In mice, the implant induced cervical-uterine tumors, which metastasized in some cases. There is suggestive evidence that injection of testosterone into some strains of female mice increases their susceptibility to hepatoma. Testosterone is also known to increase the number of tumors and decrease the degree of differentiation of chemically induced carcinomas of the liver in rats.

Human Data: There are rare reports of hepatocellular carcinoma in patients receiving long-term oral therapy with androgens in high doses. Withdrawal of the drugs did not lead to regression of the tumors in all cases.

Geriatric patients treated with androgens may be at an increased risk for the development of prostatic hyperplasia and prostatic carcinoma. Geriatric patients and other patients with clinical or demographic characteristics that are recognized to be associated with an increased risk of prostate cancer should be evaluated for the presence of prostate cancer prior to initiation of testosterone replacement therapy.

In men receiving testosterone replacement therapy, surveillance for prostate cancer should be consistent with current practices for eugonadal men.

Pregnancy Category X (see Contraindications) – Teratogenic Effects: Testim® is not indicated for women and must not be used in women. Testosterone may cause fetal harm.

Nursing Mothers: Testim® is not indicated for women and must not be used in nursing mothers.

Pediatric Use: Safety and efficacy of Testim® in patients <18 years old has not been established.

ADVERSE REACTIONS

In a controlled clinical study, 304 patients were treated with Testim® 50 mg or 100 mg or placebo gel for up to 90 days. Two hundred-five (205) patients received Testim® 50 mg or 100 mg daily and 99 patients received placebo. Patients with adverse events that were possibly or probably related to study drug and reported by ≥1% of the Testim® patients and greater than placebo are listed in Table 3.

Table 3: Incidence of Adverse Events Judged Possibly, Probably or Definitely Related to Use of Testim® in the Controlled Clinical Trial

Event	Testim® 50 mg	Testim® 100 mg	Placebo
Application Site Reactions	2%	4%	3%
Benign Prostatic Hyperplasia	0%	1%	1%
Blood Pressure Diastolic Decreased	1%	0%	0%
Blood Pressure Increased	1%	1%	0%
Gynecomastia	1%	0%	0%
Headache	1%	1%	0%
Hematocrit/hemoglobin Increased	1%	2%	0%
Hot Flushes	1%	0%	0%
Insomnia	1%	0%	0%
Lacrimation Increased	1%	0%	0%
Mood Swings	1%	0%	0%
Smell Disorder	1%	0%	0%
Spontaneous Penile Erection	1%	0%	0%
Taste Disorder	1%	1%	0%

The following adverse events possibly or probably related to Testim® occurred in fewer than 1% of patients but were greater in Testim® groups compared to the placebo group: activated partial thromboplastin time prolonged, blood creatinine increased, prothrombin time prolonged, appetite increased, sensitive nipples, and acne.

In this clinical trial of Testim®, six patients had adverse events that led to their discontinuation. These events included: vertigo, coronary artery disease, depression with suicidal ideation, urinary tract infection/pneumonia (none of which were considered related to Testim® administration), mood swings and hypertension. No Testim® patients discontinued due to skin reaction.

In one foreign Phase 3 trial, one subject discontinued due to a skin-related adverse event. In the pivotal U.S. and European Phase 3 trials combined, at the 50 mg dosage strength, the percentage of subjects reporting clinically notable increases in hematocrit or hemoglobin were similar to

placebo. However, in the 100 mg dose group, 2.3% and 2.8% of patients had a clinically notable increase in hemoglobin (≥ 19 gm/dL) or hematocrit (≥ 58%), respectively.

In the combined ongoing U.S. and European open label extension studies, approximately 140 patients received Testim® for at least 6 months. The preliminary results from these studies are consistent with those reported for the U.S. controlled clinical trial.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of testosterone gel products. Because the reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Secondary Exposure to Testosterone in Children

Cases of secondary exposure to testosterone resulting in virilization of children have been reported in postmarketing surveillance of testosterone gel products. Signs and symptoms of these reported cases have included enlargement of the clitoris (with surgical intervention) or of the penis, development of pubic hair, increased erections and libido, aggressive behavior, and advanced bone age. In most cases with a reported outcome, these signs and symptoms were reported to have regressed with removal of the testosterone gel exposure. In a few cases, however, enlarged genitalia did not fully return to age-appropriate normal size, and bone age remained modestly greater than chronological age. In some of the cases, direct contact with the sites of application on the skin of men using testosterone gel was reported. In at least one reported case, the reporter considered the possibility of secondary exposure from items such as the testosterone gel user's shirts and/or other fabrics, such as towels and sheets (see WARNINGS).

DRUG ABUSE AND DEPENDENCE

Testim® contains testosterone, a Schedule III controlled substance as defined by the Anabolic Steroids Control Act. Oral ingestion of Testim® will not result in clinically significant serum testosterone concentrations due to extensive first-pass metabolism.

OVERDOSAGE

There were no reports of overdose in the Testim® clinical trials. There is one report of acute overdosage by injection of testosterone enanthate: testosterone levels of up to 11,400 ng/dL were implicated in a cerebrovascular accident.

DOSAGE AND ADMINISTRATION

The recommended starting dose of Testim® is 5 g of gel (one tube) containing 50 mg of testosterone applied once daily (preferably in the morning) to clean, dry intact skin of the shoulders and/or upper arms (area of application should be limited to the area that will be covered by the patient's short sleeve t-shirt). Morning serum testosterone levels should then be measured approximately 14 days after initiation of therapy to ensure proper serum testosterone levels are achieved. If the serum testosterone concentration is below the normal range, or if the desired clinical response is not achieved, the daily Testim® dose may be increased from 5 g (one tube) to 10 g (two tubes) as instructed by the physician.

Upon opening the tube the entire contents should be squeezed into the palm of the hand and immediately applied to the shoulders and/or upper arms (area of application should be limited to the area that will be covered by the patient's short sleeve t-shirt). Application sites should be allowed to dry for a few minutes prior to dressing. Hands should be washed thoroughly with soap and water after Testim® has been applied.

In order to prevent transfer to another person, clothing should be worn to cover the application sites. If direct skin-to-skin contact with another person is anticipated, the application sites must be washed thoroughly with soap and water.

In order to maintain serum testosterone levels in the normal range, the sites of application should not be washed for at least two hours after application of Testim®.

Do not apply Testim® to the genitals or to the abdomen.

HOW SUPPLIED

Testim® contains testosterone, a Schedule III controlled substance as defined by the Anabolic Steroids Control Act. Testim® is supplied in unit-dose tubes in cartons of 30. Each tube contains 50 mg testosterone in 5 g of gel, and is supplied as follows:

NDC Number	Strength	Package Size
66887-001-05	1% (50 mg)	30 tubes: 5 g per tube

Storage

Store at room temperature 25°C (77°F); Excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].

Disposal

Keep out of the reach of children.

Used Testim® tubes should be discarded in household trash in a manner that prevents accidental exposure of children or pets; contents flammable.

RX Only

Manufactured for:
Auxilium Pharmaceuticals, Inc.
Malvern, PA 19355 USA
By: Contract Pharmaceuticals Limited
Mississauga, Ontario, Canada L5N 6L6

EXHIBIT C

TESTOPEL- testosterone pellet
Slate Pharma

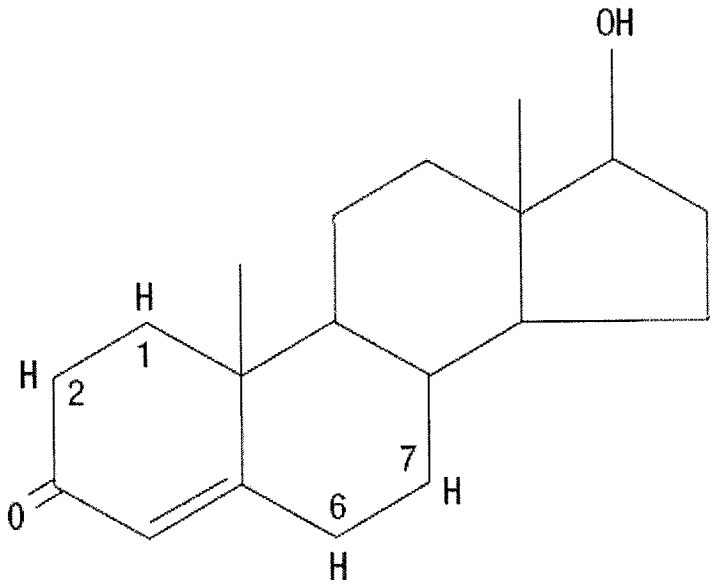
DESCRIPTION

TESTOPEL® Pellets (testosterone) are cylindrically shaped pellets 3.2mm (1/8 inch) in diameter and approximately 9mm in length. Each sterile pellet weighs approximately 78mg (75mg testosterone) and is ready for implantation.

Androgens are steroids that develop and maintain primary and secondary male sex characteristics. Testosterone is a member of this class.

Structural formula for testosterone follows:

TESTOSTERONE
$C_{19}H_{28}O_2$ MW288.43
17ß -Hydroxyandrost-4-en-3-one



INGREDIENTS

Each **TESTOPEL®** Pellet (testosterone) for subcutaneous implantation contains 75mg testosterone. In addition each pellet contains the following inactive ingredients: stearic acid NF 0.97mg and polyvinylpyrrolidone USP 2mg.

TESTOPEL® Pellets (testosterone) consist of crystalline testosterone. When implanted subcutaneously, the pellets slowly release the hormone for a long acting androgenic effect.

CLINICAL PHARMACOLOGY

Endogenous androgens are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. These effects include the growth and maturation of prostate, seminal vesicles, penis and scrotum; the development of male hair distribution such as beard, pubic, chest and axillary hair, laryngeal enlargements, vocal cord thickening, alterations in body musculature and fat distribution. Drugs in this class can also cause retention of nitrogen, sodium,

potassium, phosphorus, and decreased urinary excretion of calcium.

Androgens have been reported to increase protein anabolism and decrease protein catabolism.

Nitrogen balance is improved only when there is sufficient intake of calories and protein.

Androgens are responsible for the growth spurt of adolescence and for the eventual termination of linear growth which is brought about by the fusion of the epiphyseal growth centers. In children, exogenous androgens accelerate linear growth rates, but may cause a disproportionate advancement in bone maturation. Use over long periods may result in fusion of the epiphyseal growth centers and termination of growth process. Androgens have been reported to stimulate the production of red blood cells by enhancing the production of erythropoietic stimulating factor.

During exogenous administration of androgens, endogenous testosterone release is inhibited through feedback inhibition of pituitary luteinizing hormone (LH). At large doses of exogenous androgens, spermatogenesis may also be suppressed through feedback inhibition of pituitary follicle stimulating hormone (FSH).

There is a lack of substantial evidence that androgens are effective in fractures, surgery, convalescence, and functional uterine bleeding.

PHARMACOKINETICS

Testosterone in plasma is 98 percent bound to a specific testosterone-estradiol binding globulin, and about 2 percent is free. Generally, the amount of this sex-hormone binding globulin in the plasma will determine the distribution of testosterone between the free and bound forms, and the free testosterone concentration will determine its half-life.

About 90 percent of a dose of testosterone is excreted as glucuronic and sulfuric acid conjugates of testosterone and its metabolites; about 6 percent of a dose is excreted in feces, mostly in the unconjugated form. Inactivation of testosterone occurs primarily in the liver. Testosterone is metabolized to various 17-keto steroids through two different pathways. There are considerable variations of the half-life as reported in the literature, ranging from 10-100 minutes.

In many tissues the activity of testosterone appears to depend on reduction to dihydrotestosterone, which binds to cytosol receptor proteins. The steroid-receptor complex is transported to the nucleus where it initiates transcription events and cellular changes related to androgen action.

INDICATIONS AND USAGE

MALES

Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

a. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy.
b. Hypogonadotrophic hypogonadism (congenital or acquired) - idiopathic or gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation.

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

c. Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief

treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An x-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal centers (see WARNINGS).

CONTRAINDICATIONS

Androgens are contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate. If administered to pregnant women, androgens cause virilization of the external genitalia of the female fetus. The virilization includes clitoromegaly, abnormal vaginal development, and fusion of genital folds to form a scrotal-like structure. The degree of masculinization is related to the amount of drug given and the age of the fetus, and is most likely to occur in the female fetus when the drugs are given in the first trimester. If the patient becomes pregnant while taking these drugs she should be apprised of the potential hazard to the fetus.

WARNINGS

In patients with breast cancer, androgen therapy may cause hypercalcemia by stimulating osteolysis. In this case, the drug should be discontinued.

Prolonged use of high doses of androgens has been associated with the development of peliosis hepatitis and hepatic neoplasms including hepatocellular carcinoma (see PRECAUTIONS - Carcinogenesis, Mutagenesis, Impairment of Fertility). Peliosis hepatitis can be a life-threatening or fatal complication.

Men treated with androgens may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma.

Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required.

Gynecomastia frequently develops in patients and occasionally persists in patients being treated for hypogonadism.

Androgen therapy should be used cautiously in healthy males with delayed puberty. The effect on bone maturation should be monitored by assessing bone age of the wrist and hand every 6 months. In children, androgen treatment may accelerate bone maturation without producing compensatory gain in linear growth. This adverse effect may result in compromised adult stature. The younger the child the greater the risk of compromising final mature height.

This drug has not been shown to be safe and effective for the enhancement of athletic performance. Because of the potential risk for serious adverse health effects, this drug should not be used for such purpose.

PRECAUTIONS

GENERAL

Pellet implantation is much less flexible for dosage adjustment than is oral administration of or intramuscular injections of oil solutions or aqueous suspensions. Therefore, great care should be used when estimating the amount of testosterone needed.

In the face of complications where the effects of testosterone should be discontinued, the pellets would

have to be removed. In addition, there are times when the pellets may slough out. This accident is usually traceable to superficial implantation or neglect in regard to aseptic precautions.

INFORMATION FOR THE PATIENT

The physician should instruct patients to report any of the following side effects of androgens:

Adult or adolescent males: Too frequent or persistent erections of the penis. Any nausea, vomiting, changes in skin color, ankle swelling.

Any male adolescent patient receiving androgens for delayed puberty should have bone development checked every 6 months.

LABORATORY TESTS

1. Because of the hepatotoxicity associated with the use of 17-alpha-alkylated androgens, liver function tests should be obtained periodically.
2. Periodic (every 6 months) x-ray examinations of the bone age should be made during treatment of prepubertal males to determine the rate of bone maturation and the effects of androgen therapy on the epiphyseal centers.
3. Hemoglobin and hematocrit should be checked periodically for polycythemia in patients who are receiving high doses of androgens.

DRUG INTERACTIONS

1. Anticoagulants. C-17 substituted derivatives of testosterone, such as methandrostenolone have been reported to decrease the anticoagulant requirements of patients receiving oral anticoagulants. Patients receiving oral anticoagulant therapy require close monitoring, especially when androgens are started or stopped.
2. Oxyphenbutazone. Concurrent administration of oxyphenbutazone and androgens may result in elevated serum levels of oxyphenbutazone.
3. Insulin. In diabetic patients the metabolic effects of androgens may decrease blood glucose and insulin requirements.

DRUG/LABORATORY TEST INTERFERENCES

Androgens may decrease levels of thyroxine-binding globulin, resulting in decreased total T_4 serum levels and increased resin uptake of T_3 and T_4. Free thyroid hormone levels remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

Animal Data. Testosterone has been tested by subcutaneous injection and implantation in mice and rats. The implant induced cervical-uterine tumors in mice, which metastasized in some cases. There is suggestive evidence that injection of testosterone into some strains of female mice increases their susceptibility to hepatoma. Testosterone is also known to increase the number of tumors and decrease the degree of differentiation of chemically induced carcinomas of liver in rats.

Human Data. There are rare reports of hepatocellular carcinoma in patients receiving long-term therapy with androgens in high doses. Withdrawal of the drugs did not lead to regression of the tumors in all cases.

Geriatric patients treated with androgens may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma.

PREGNANCY

Teratogenic Effects. Pregnancy Category X (see CONTRAINDICATIONS).

NURSING MOTHERS

It is not known whether androgens are excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from androgens, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

PEDIATRIC USE

Androgen therapy should be used very cautiously in children and only by specialists who are aware of the adverse effects on bone maturation. Skeletal maturation must be monitored every 6 months by an x-ray of the hand and wrist (see INDICATIONS AND USAGE and WARNINGS).

ADVERSE REACTIONS

Endocrine and Urogenital
Male. Gynecomastia and excessive frequency and duration of penile erections. Oligospermia may occur at high dosages (see CLINICAL PHARMACOLOGY).

Skin and Appendages. Hirsutism, male pattern of baldness, and acne.

Fluid and Electrolyte Disturbances. Retention of sodium, chloride, water, potassium, calcium and inorganic phosphates.

Gastrointestinal. Nausea, cholestatic jaundice, alterations in liver function tests, rarely hepatocellular neoplasms and peliosis hepatitis (see WARNINGS).

Hematologic. Suppression of clotting factors II, V, VII, and X, bleeding in patients on concomitant anticoagulant therapy, and polycythemia.

Nervous System. Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia.

Metabolic. Increased serum cholesterol.

Miscellaneous. Inflammation and pain at the site of subcutaneous implantation of testosterone containing pellets, and rarely anaphylactoid reactions.

DRUG ABUSE AND DEPENDENCE

Testosterone pellets are classified as a Schedule III controlled substance under the Anabolic Steroids Act of 1990.

OVERDOSAGE

There have been no reports of acute overdosage with the androgens.

DOSAGE AND ADMINISTRATION

The suggested dosage for androgens varies depending on the age, and diagnosis of the individual patient. Dosage is adjusted according to the patient's response and the appearance of adverse reactions. The dosage guideline for the testosterone pellets for replacement therapy in androgen-deficient males is 150mg to 450mg subcutaneously every 3 to 6 months. Various dosage regimens have been used to induce pubertal changes in hypogonadal males; some experts have advocated lower doses initially,

gradually increasing the dose as puberty progresses, with or without a decrease in maintenance levels. Other experts emphasize that higher dosages are needed to induce pubertal changes and lower dosages can be used for maintenance after puberty. The chronological and skeletal ages must be taken into consideration, both in determining the initial dose and in adjusting the dose.

Dosages in delayed puberty generally are in the lower range of that listed above and, for a limited duration, for example 4 to 6 months.

The number of pellets to be implanted depends upon the minimal daily requirements of testosterone propionate determined by a gradual reduction of the amount administered parenterally. The usual dosage is as follows: implant two 75mg pellets for each 25mg testosterone propionate required weekly. Thus when a patient requires injections of 75mg per week, it is usually necessary to implant 450mg (6 pellets). With injections of 50mg per week, implantation of 300mg (4 pellets) may suffice for approximately three months. With lower requirements by injection, correspondingly lower amounts may be implanted. It has been found that approximately one-third of the material is absorbed in the first month, one-fourth in the second month and one-sixth in the third month. Adequate effect of the pellets ordinarily continues for three to four months, sometimes as long as six months.

HOW SUPPLIED

Testosterone pellets of 75mg. One pellet per vial in boxes of 10 (NDC: 43773-1001-2) and 100 (NDC: 43773-1001-3). Store in a cool dry place.

Rx Only

Manufactured by **Bartor Pharmacal**
70 High St., Rye, N.Y. 10580

Rev. 3 1/2013

Principal Display Panel – 100 Pellets

100 Pellets
Sterile

NDC 43773-1001-3

TESTOPEL® 75mg
(testosterone pellets) CIII

For subcutaneous implantation
Each pellet contains:
75mg testosterone
In addition, each pellet contains the following inactive ingredients:
Stearic Acid NF 0.97mg and Polyvinylpyrrolidone USP 2mg.

Usual Dosage: See package insert.

Rx Only.
75mg Brand of Testosterone

Manufactured by **Bartor Pharmacal**

70 High St., Rye N.Y. 10580

Marketed by:
Slate pharmaceuticals, Inc.

TESTOPEL

testosterone pellet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:43773-1001
Route of Administration	SUBCUTANEOUS	**DEA Schedule**	CIII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TESTOSTERONE (TESTOSTERONE)	TESTOSTERONE	75 mg

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID	0.97 mg
POVIDONE K30	2 mg

Product Characteristics

Color	WHITE	**Score**	
Shape	BULLET (Cylindrical)	**Size**	9mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43773-1001-2	10 in 1 BOX		
1		1 in 1 AMPULE		
2	NDC:43773-1001-3	100 in 1 BOX		
2		1 in 1 AMPULE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080911	07/21/2009	

Labeler - Slate Pharma (005232743)

Establishment

Name	Address	ID/FEI	Business Operations
Bartor Pharmacal		001561174	MANUFACTURE(43773-1001)

Revised: 6/2013

Slate Pharma

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: ANDROGEL PRODUCTS LIABILITY LITIGATION	:	**MDL DOCKET NO. 2545**

CERTIFICATE OF SERVICE

On April 25, 2014, I electronically filed a copy of foregoing through the CM/ECF system, which will send a notice of electronic filing to the attorneys listed below; and I served by First-Class U.S. Mail the foregoing and the notice of electronic filing where noted upon the attorneys listed below:

ATTORNEY	PARTY / CASE
James F. Hurst Nicole E. Wrigley Scott P. Glauberman Bryna Joyce Roth Dahlin Joseph Laurence Motto Scott M. Ahmad Thomas James Frederick **Winston & Strawn, LLP** 35 W. Wacker Dr. Chicago, IL 60601-9703 jhurst@winston.com nwrigley@winston.com sglauber@winston.com bdahlin@winston.com jmotto@winston.com sahmad@winston.com Tfrederick@winston.com	Defendants: AbbVie Inc. and Abbott Laboratories, Inc. *Aurecchia v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-772 *Marino v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-777 *Myers v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-780 *Johnson v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-877 *Kelly, Sr. v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-879 *Lau v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-1298 *Cripe v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-843 *Gibby v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-917 *Hardee v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-918 *Bartholic v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-1427 *O'Donnell v. AbbVie Inc., et al.*, N.D.Il., No. 1:14-cv-1428

ATTORNEY	PARTY / CASE
	Blades v. AbbVie Inc., et al., N.D.Il., No. 1:14-cv-1471 *Carpenter v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1472 *Humphries v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1473 *Dobbs v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1474 *Headley v. AbbVie Inc., et al.* N.D.Il., No. 1:14-cv-1475 *Hughes v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1476 *Jackson v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1477 *Gordon v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1478 *Jones v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1479 *King v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1480 *Lewis v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1481 *Saylor v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1482 *Cataudella v. AbbVie Inc., et al.,* N.D.Il., No.1:14-cv-1483 *Bailey v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1663 *Gordon v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1665 *White v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1667 *Montgomery v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1668 *Ortiz v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1670 *DeLeon v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-167 *Delu v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1726 *LaRoche v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1826 *George v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2085 *Darby v. AbbVie Inc., et al.,*

ATTORNEY	PARTY / CASE
	N.D.Il., No. 1-1:14-cv-cv-2227 *Emmons v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2221 *Covey v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2406 *Parker v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2394 *Deforest v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2405 *Lueck v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2140 *Schenkein v. AbbVie Inc., et al.,* D.Co., No. 1:14-cv-910 *Tejeda v. AbbVie Inc., et al.,* E.D.Pa., No. 2:14-cv-946 *LoCoco v. AbbVie Inc., et al.,* E.D.La., No. 2:14-cv-774 *Albright v. AbbVie Inc., et al,* E.D.La., No. 1:14-cv-2112 *Harris v. AbbVie Inc., et al,* E.D. Pa., No. 1:14-cv-2113 *Husted v. AbbVie Inc., et al,* E.D. Pa., No. 1:14-cv-2111 *Komrada v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2429 *Mecikalski v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2441 *Reid v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2443 *Spann v. AbbVie Inc., et al.,* E.D.La., 3:14-cv-935 *Young v. Abbvie Inc., et al.,* N.D.Il., No. 1:14-cv-02829 *Couwenhoven v. Abbott Laboratories, Inc., et al.,* C.D.Ca., No. 5:14-cv-667 *Schwalm v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2899

ATTORNEY	PARTY / CASE
David E. Stanley **Reed Smith LLP** 355. S. Grand Avenue, Suite 2900 Los Angeles, CA 90071 Dstanley@reedsmith.com Timothy Robert Carraher **Reed Smith LLP** 10 S. Wacker Dr., 40th Floor Chicago, IL 60606 tcarraher@reedsmith.com	Defendants: Eli Lilly and Company, Lilly USA LLC *Lau v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1298 ***Filing Served by U.S. Mail***
Andrew Keith Solow **Kaye Scholer LLP** 425 Park Ave. New York, NY 10022 asolow@kayescholer.com Jeffrey Mark Wagner **Kaye Scholer LLP** 3 First National Plaza 70 West Madison Chicago, IL 60602 Jeffrey.wagner@kayescholer.com Pamela Joan Yates **Kaye Scholer LLP** 1999 Avenue of the Stars, Suite 1700 Los Angeles, CA 90067 pyates@kayescholer.com	Defendant: Endo Pharmaceuticals *Cataudella v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1483 ***Filing Served by U.S. Mail***
AbbVie, Inc. c/o CT Corporation System 5615 Corporate Boulevard, Suite 400B Baton Rouge, LA 70808 **Abbott Laboratories, Inc.** c/o CT Corporation System 5615 Corporate Boulevard, Suite 400B Baton Rouge, LA 70808	Defendant: *Barrios v. AbbVie Inc., et al.,* E.D., LA, No. 2:14-cv-00839 *Spann v. AbbVie Inc., et al.,* E.D.La., 3:14-cv-935 ***Filing Served by U.S. Mail***

ATTORNEY	PARTY / CASE
Joseph P. Thomas **Ulmer & Berne LLP** 600 Vine Street, Suite 2800 Cincinnati, OH 45202 jthomas@ulmer.com	Defendants: Actavis, Inc. (f/k/a Watson Pharmaceuticals, Inc.) Anda, Inc. *Hall v. Actavis Plc., et al.* NV, No. 2:14-cv-00453 *McGill v. Actavis, Inc., et al.* E.D.Pa., No. 2:14-cv-02177 *Couwenhoven v. Abbott Laboratories, Inc., et al.,* C.D.Ca., No. 5:14-cv-667 *Davis v. Actavis Pharma, Inc., et al.,* NV, No. 2:14-cv-00596 *Schwalm v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2899
Physicians Total Care, Inc. c/o National Corporate Research, Ltd. 1833 S. Morgan Road Oklahoma City, OK 73218	Defendant: *Davis v. Actavis Pharma, Inc., et al.,* NV, No. 2:14-cv-00596 ***Filing Served by U.S. Mail***
Actavis plc. 1 Grand Canal Square Dockland, Dublin 2 Ireland Actavis Pharma, Inc. c/o The Corporation Trust Company of Nevada 311 S. Division Street Carson City, NY 89703 Anda, Inc. 2915 Weston Road Weston, FL 33331 Watson Laboratories c/o The Corporation Trust Company of Nevada 311 S. Division Street Carson City, NY 89703	Defendants: *Davis v. Actavis Pharma, Inc., et al.,* NV, No. 2:14-cv-00596 ***Filing Served by U.S. Mail***

ATTORNEY	PARTY / CASE
Abbott Laboratories, Inc. 100 Abbott Park Road Abbott Park, IL 60064-3500 AbbVie Inc. 1 North Waukegan Road North Chicago, IL 60064 Pfizer Inc. 235 East 42nd Street New York, NY 10017	Defendants: *Amerson v. Abbott Laboratories Inc., et al.,* E.D.Pa., No. 2:14-cv-02206 ***Filing Served by U.S. Mail***
AbbVie Inc. 1 North Waukegan Road North Chicago, IL 60064 Abbott Laboratories, Inc. 100 Abbott Park Road Abbott Park, IL 60064-3500	Defendants: *Runyan v. AbbVie Inc., et al.,* E.D.La., No. 2:14-cv-00909 ***Filing Served by U.S. Mail***
Lee A. Cirsch Michael A. Akselrud **The Lanier Law Firm PC** 2049 Century Park East, Suite 1940 Los Angeles, CA 90067 lee.cirsch@lanierlawfirm.com michael.akselrud@lanierlawfirm.com Richard D. Meadow W. Mark Lanier Catherine Heacox **The Lanier Law Firm PLLC** 126 East 56th Street, 6th Floor New York, NY 10022 wml@lanierlawfirm.com catherine.heacox@lanierlawfirm.com rdm@lanierlawfirm.com	Plaintiffs: *Couwenhoven v. Abbott Laboratories, Inc., et al.,* C.D.Ca., No. 5:14-cv-667 *Amerson v. Abbott Laboratories Inc., et al.,* E.D.Pa., No. 2:14-cv-02206 ***Filing Served by U.S. Mail***
Diane Nast **NastLaw LLC** 1101 Market St., Suite 2801 Philadelphia, PA 19107 Dnast@nastlaw.com	Plaintiff: *Tejeda v. AbbVie Inc., et al.,* E.D.Pa., No. 2:14-cv-946 *Hill v. Auxilium Pharmaceuticals, Inc.,* E.D., Pa., No. 2:14-cv-02189

ATTORNEY	PARTY / CASE
Gerald E. Meunier **Gainsburgh, Benjamin, David, Meunier & Warshauer** Energy Centre 1100 Poydras Street, Suite 2800 New Orleans, LA 70163-2800 gmeunier@gainsben.com	Plaintiff: *LoCoco v. AbbVie Inc., et al.,* E.D.La., No. 2:14-cv-774 ***Filing Served by U.S. Mail***
Ronald E. Johnson, Jr. Sarah Lynch **Schachter Hendy & Johnson** 909 Wrights Summit Parkway, Suite 210 Fort Wright, KY 41011 rjohnson@pschachter.com slynch@pschachter.com	Plaintiffs: *Blades v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1471 *Carpenter v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1472 *Cataudella v. AbbVie Inc., et al.,* N.D.Il., No 1:14-cv-01483 *Cripe v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-843 *Dobbs v. AbbVie Inc., et al.* N.D.Il., No. 1:14-cv-1474 *Gibby v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-917 *Gordon v. AbbVie Inc., et al.,* N.D.Il., No. 1-14-cv-1478 *Hardee v. AbbVie Inc., et al.,* N.D.Il, No. 1-14-cv-918 *Headley v. AbbVie Inc., et al.,* N.D.Il., No. 1-14-cv-1475 *Hughes v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1476 *Humphries v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1473 *Jackson v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1477 *Jones v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1479 *King v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1480 *Lewis v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1481 *Saylor v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1482 *Ott v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-02495 *Ousley v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-02729

ATTORNEY	PARTY / CASE
	In re AbbVie Inc., et al., N.D.Il., No. 1:14-cv-01748 ***Filing Served by U.S. Mail***
John Sawin **Sawin Law Firm, Ltd.** 55 W Wacker Drive, Floor 9 Chicago, IL 60601-1794 jsawin@sawinlawyers.com	Plaintiffs: *Blades v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1471 *Carpenter v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv--1472 *Cataudella v. AbbVie Inc., et al.,* N.D.Il., No 1:14-cv-01483 *Cripe v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-843 *Dobbs v. AbbVie Inc., et al.* N.D.Il., No. 1:14-cv-1474 *Gibby v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-917 *Gordon v. AbbVie Inc., et al.,* N.D.Il., No. 1-14-cv-1478 *Hardee v. AbbVie Inc., et al.,* N.D.Il, No. 1-14-cv-918 *Headley v. AbbVie Inc., et al.,* N.D.Il., No. 1-14-cv-1475 *Hughes v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1476 *Humphries v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1473 *Jackson v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1477 *Jones v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1479 *King v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1480 *Lewis v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1481 *Saylor v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1482 *Ott v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-02495 *Ousley v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-02729 *In re AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-01748 ***Filing Served by U.S. Mail***

ATTORNEY	PARTY / CASE
Scott Morgan **Morgan Law Firm, Ltd.** 55 W. Wacker Drive, Suite 900 Chicago, IL 60601-1794 smorgan@smorgan-law.com	Plaintiffs: *Blades v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1471 *Carpenter v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv--1472 *Cataudella v. AbbVie Inc., et al.,* N.D.Il., No 1:14-cv-01483 *Cripe v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-843 *Dobbs v. AbbVie Inc., et al.* N.D.Il., No. 1:14-cv-1474 *Gibby v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-917 *Gordon v. AbbVie Inc., et al.,* N.D.Il., No. 1-14-cv-1478 *Hardee v. AbbVie Inc., et al.,* N.D.Il, No. 1-14-cv-918 *Headley v. AbbVie Inc., et al.,* N.D.Il., No. 1-14-cv-1475 *Hughes v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1476 *Humphries v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1473 *Jackson v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1477 *Jones v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1479 *King v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1480 *Lewis v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1481 *Saylor v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1482 *Ott v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-02495 *Ousley v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-02729 *In re AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-01748 ***Filing Served by U.S. Mail***

ATTORNEY	PARTY / CASE
Seth A. Katz **Burg Simpson** 40 Iverness Drive East Englewood, CO 80116 skatz@burgsimpson.com	Plaintiffs: *Schenkein v. AbbVie Inc., et al.,* D.Co., No. 1:14-cv-910 ***Filing Served by U.S. Mail***
Joseph M. Lyon **The Lyon Firm** 22 West 9th Cincinnati, OH 45202 jlyon@thelyonfirm.com	Plaintiffs: *Cripe v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-843 *Gibby v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-917 *Hardee v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-918 *Dobbs v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1474 *Headley v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1475 *Hughes v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1476 *Jackson v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1477 *Gordon v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1478 *Jones v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1479 *King v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1480 *Lewis v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1481 *Saylor v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1482 ***Filing Served by U.S. Mail***
Trent B. Miracle Brendan A. Smith **Simmons Browder Gianaris Angelides & Barnerd** One Court Street Alton, IL 62002 tmiracle@simmonsfirm.com	Plaintiffs: *Aurecchia v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-772 *Bailey v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1663 *Bartholic v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1427 *Cole v. AbbVie Inc., et al.* N.D.Il., No. 1:14-cv-2613 *DeLeon v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-167

ATTORNEY	PARTY / CASE
	Delu v. AbbVie Inc., et al., N.D.Il., No. 1:14-cv-1726 *George v. AbbVie Inc., et al.,* N.D.Il., No. 1:14cv-2085 *Gordon v. AbbVie Inc., et al.,* N.D.Il., No. 1-14-cv-1665 *Johnson v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-877 *Kanady v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2612 *Kelly, Sr. v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-879 *Lane v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2611 *Lau v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1298 *Lueck v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2140 *Marino v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-777 *Montgomery v. AbbVie Inc., et al.* N.D.Il, No. 1:14-cv-1668 *Myers v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-780 *O'Donnell v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1428 *Ortiz v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1670 *Pointer v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2633 *Udovich v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2629 *White v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1667 *Schwalm v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2899 *Davis v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-02774 ***Filing Served by U.S. Mail***

ATTORNEY	PARTY / CASE
Benedict P. Morelli David Stuart Ratner David T. Sirotkin **Morelli Alters Ratner LLP** 950 Third Ave., 11th Floor New York, NY 10022 bmorelli@morellialters.com dratner@morellialters.com dsirotkin@morellialters.com	Co-Counsel for Plaintiffs: *Aurecchia v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-772 *Marino v. AbbVie Inc., et al.,* N.D.Il.,No. 1:14-cv-777 *Myers v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-780 *Bailey v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1663 *DeLeon v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-167 *Gordon v. AbbVie Inc., et al.,* N.D.Il., No. 1-14-cv-1665 *Marino v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-777 *Montgomery v. AbbVie Inc., et al.* N.D.Il, No. 1:14-cv-1668 *Myers v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-780 *White v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-1667 *In re AbbVie Inc., et al.* N.D.Il., No. 1:14-cv-01748 ***Filing Served by U.S. Mail***
James P. Roy Elwood C. Stevens, Jr. **Domengeaux, Wright, Roy & Edwards** 556 Jefferson St., Suite 500 Lafayette, LA 70502 jimr@wrightroy.com ElwoodS@wrightroy.com	Plaintiff: *Peuler v. Auxilium Pharmaceuticals,* E.D.La., No. 14-658
Drew B. LaFramboise James F. Green Stephanie Lynn Gardner **Ashcraft & Gerel, LLP** 4900 Seminary Rd., Suite 650 Alexandria, VA 22311 dlaframboise@ashcraftlaw.com jgreen@ashcraftlaw.com sgardner@ashcraftlaw.com mparf@aol.com	Plaintiff: *Komrada v. AbbVie Inc., et al.,* N.D.Il., No. 14-2429 ***Filing Served by U.S. Mail***

ATTORNEY	PARTY / CASE
Tor A. Hoerman **TorHoerman Law LLC** 101 W. Vandalia St., Suite 350 Edwardsville, IL 62025 thoerman@torhoermanlaw.com	Plaintiff: *Komrada v. AbbVie Inc., et al.,* N.D.Il., No. 14-2429 ***Filing Served by U.S. Mail***
Gary D. McCallister **Gary D. McCallister & Associates, LLC** 120 N. LaSalle Street, Suite 2800 Chicago, IL 60602 gdm@gdmlawfirm.com	Plaintiff: *Mecikalski v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2441 *Reid v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2443 ***Filing Served by U.S. Mail***
George M. Fleming Rand P. Nolen **Fleming, Nolen & Jez LLP** 2800 Post Oak Boulevard, Suite 4000 Houston, TX 77056-6109 georgefleming@fleming-law.com	Plaintiff: *Mecikalski v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2441 *Reid v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-2443 ***Filing Served by U.S. Mail***
Arnold Levin Michael M. Weinkowitz **Levin, Fishbein, Sedran & Berman** 510 Walnut Street, Suite 500 Philadelphia, PA 19104 mweinkowitz@lfsblaw.com alevin@lfsblaw.com	Plaintiff: *Albright v. AbbVie Inc., et al.,* E.D.Pa., No. 2:14-cv-2112 *Harris v. AbbVie Inc., et al,* E.D. Pa., No. 2:14-cv-2113 *Husted v. AbbVie Inc., et al,* E.D. Pa., No. 2:14-cv-2111 *McGill v. Actavis, Inc., et al.* E.D.Pa., No. 2:14-cv-2177 ***Filing Served by U.S. Mail***
Maury A. Herman Aaron Z. Ahlquist Leonard A. Davis **Herman, Herman & Katz, LLC** 820 O'Keefe Avenue New Orleans, LA 70113 mherman@hhklawfirm.com aahlquist@hhklawfirm.com ldavis@hhklawfirm.com	Plaintiff: *Barrios v. AbbVie Inc., et al.,* E.D., LA, No. 2:14-cv-00839

ATTORNEY	PARTY / CASE
Myron Milton Cherry **Myron M. Cherry & Associates** 30 North LaSalle Street, Suite 2300 Chicago, IL 60602 mcherry@cherry-law.com	Plaintiff: *Emmons v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-02221 *Parker v. AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-02394 *In re AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-01748
Michelle L. Kranz James Griffin O'Brien **Zoll, Kranz & Borgess, LLC** 6620 West Central Avenue, Suite 100 Toledo, OH 43617 jim@toledolaw.com michelle@toledolaw.com	Plaintiff: *Darby v. AbbVie Inc., et al.,* N.D.Il., No. 1-14-cv-2227 *In re AbbVie Inc., et al.,* N.D.Il., No. 1:14-cv-01748 *Davis v. Actavis Pharma, Inc., et al.* NV, No.: 2-14-cv-00596
Don Springmeyer **Wolf Rifkin Shapiro Schulman Rabkin, LLP** 3556 East Russell Road, Second Floor Las Vegas, NV 89120 DSpringmeyer@wrslawyers.com	Plaintiff: *Davis v. Actavis Pharma, Inc., et al.* NV, No.: 2-14-cv-00596 *Hall v. Actavis Plc., et al.* NV, No. 2:14-cv-00453 ***Filing Served by U.S. Mail***
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Respectfully submitted,

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