BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

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

OPPOSITION OF DEFENDANTS PFIZER INC. AND PHARMACIA & UPJOHN COMPANY LLC TO PLAINTIFFS' MOTIONS FOR TRANSFER AND COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. § 1407

Defendants Pfizer Inc. ("Pfizer") and Pharmacia & Upjohn Company LLC ("Pharmacia & Upjohn") (collectively, "the Pfizer entities") submit this opposition to Plaintiffs' motions for transfer and coordination or consolidation under 28 U.S.C. § 1407.

INTRODUCTION

The movants seek to transfer four cases against the Pfizer entities into what is likely to be a sprawling MDL proceeding involving several different manufacturers. The Pfizer entities take no position on whether an MDL proceeding should be created, but the Pfizer entities strongly believe that they should not be a part of any such proceeding. The Pfizer entities are involved in very few (only four) cases proposed for inclusion in the proposed proceeding—and those cases involve a distinct testosterone treatment that is not the gravamen of the proceeding the movants propose to create. Thus, most of the discovery and pretrial issues in the cases against the Pfizer entities will not overlap with the cases against other defendants to anywhere near the degree suggested by the movants. Most notably, plaintiffs have made clear that they seek to focus on "aggressive" direct-to-consumer television marketing of testosterone gels in this litigation, whereas the Pfizer entities have not promoted their therapy in that fashion. As a result, adding the Pfizer entities to the likely MDL proceeding will not promote the goals of 28 U.S.C. § 1407; it will not be more convenient for the parties and witnesses in the cases involving the Pfizer

entities; and it is not likely to "promote the just and efficient conduct of" the four actions. Instead, the few cases involving the Pfizer entities likely would take a back seat in any MDL proceeding, while the parties focus on common discovery and pretrial proceedings in the larger number of matters that have been filed against other defendants.

For these reasons, as discussed further below, the most expeditious course is to litigate the few cases against the Pfizer entities separately in the jurisdictions where they were filed.

BACKGROUND

Pfizer manufactures and sells, and Pharmacia & Upjohn distributes, Depo-Testosterone®, a prescription injectable testosterone therapy the FDA approved in 1979. To date, plaintiffs have filed only four cases alleging injuries as a result of Depo-Testosterone injections. The handful of cases involving the Pfizer entities are unlike the vast majority of testosterone therapy actions before this Panel, which involve recently approved topical gels such as AndroGel® (manufactured and sold by AbbVie Inc. and, at one time, Abbott Laboratories, which FDA approved in 2011), Fortesta® (Endo Pharmaceuticals Inc., approved in 2010), Axiron® (Eli Lilly and Company and Lilly USA LLC, approved in 2010), and Testim® (Auxilium Pharmaceuticals, Inc., approved in 2002). Unlike the topical gel manufacturers, the Pfizer entities offer an injectable testosterone therapy that delivers a different form of testosterone at a dose that is far lower than that delivered by the topical gels. Moreover, while the plaintiffs' allegations are focused on marketing claims relating to direct-to-consumer television advertising and unbranded campaigns, the Pfizer entities do not promote Depo-Testosterone in those ways.

ARGUMENT

Coordination of the Depo-Testosterone cases under Section 1407 at this time will neither promote "the convenience of parties and witnesses" nor "the just and efficient conduct of such

actions." 28 U.S.C. § 1407(a). On the contrary, sweeping the Pfizer entities into a sprawling MDL involving different products and different manufacturers at such an early stage risks subjecting the Pfizer entities to broader and potentially unnecessary discovery than if the few individual claims pending currently remain in their present districts.

The parties that support an industry-wide proceeding do so largely based on a small number of mixed-use cases, where plaintiffs used more than one kind of testosterone therapy.[1] But Pfizer is named in only two cases where the plaintiff also used AndroGel, and there are only two other cases where plaintiffs allege use of AndroGel and a non-gel therapy (which do not involve Pfizer).[2] That does not justify adding Pfizer to an MDL proceeding. Instead, the Pfizer entities respectfully request that the Panel: (1) limit the likely MDL proceeding to gel therapies only (or at least exclude the Pfizer entities); and (2) in the four cases in which plaintiffs used gel and non-gel therapies, sever the claims against the gel manufacturers and transfer the gel therapy claims to an MDL so that the non-gel therapy claims may proceed against the non-gel manufacturers in their present districts.[3]

A. With Only Four Cases Involving Depo-Testosterone Filed to Date, Including Cases Involving Injectable Depo-Testosterone in an MDL Primarily Focused on Gel Therapies Is Premature.

At present, only four of the eighty-five federal cases (less than five percent) involve plaintiffs who used a topical gel as well as a non-gel therapy, and only two of those cases involve the Pfizer entities. Another four cases involve plaintiffs who did not use a gel at all, two of which involve the Pfizer entities. More than ninety percent of the plaintiffs' testosterone therapy

[1] In addition to gel therapies, other testosterone therapies involved in these lawsuits include a transdermal patch known as Androderm® (sold by Actavis, Inc. and Watson Laboratories and approved by FDA in 1995) and pellets which are surgically implanted under the skin known as Testopel® (Auxilium, approved in 1972).

[2] Attached as Exhibit A is a list of the cases pending at the time of this writing, which identifies the type of testosterone therapy or therapies identified in each complaint.

[3] The only other manufacturers of non-gel testosterone therapies that have been sued in product liability litigation to date—Auxilium, Actavis and Watson—separately filed oppositions to Plaintiffs' motions to transfer.

claims—seventy-seven of the eighty-five federal claims filed as of April 29—involve some combination of topical gels only. *See* Exhibit A (listing sixty-eight cases involving only AndroGel; nine cases involving AndroGel, Axiron, Fortesta, and/or Testim; four cases involving AndroGel plus a non-gel therapy; and four cases that do not involve any use of a topical gel).

There are a number of reasons to believe that there will be far fewer Depo-Testosterone cases than those involving gel therapies. Depo-Testosterone has a relatively small share of the overall testosterone market—approximately two to three percent—and it competes with many available generic formulations of the medication. The gel therapies, by contrast, do not have generic competitors and together comprise the significant majority of testosterone prescriptions. Since 2000, moreover, the Depo-Testosterone label has had a contraindication for patients with serious cardiac disease.[4]

This Panel repeatedly has declined to establish an MDL where the litigation involves a small number of individual product liability cases. *See, e.g.*, *In re Intuitive Surgical, Inc., Da Vinci Robotic Surgical Sys. Prods. Liab. Litig.*, 883 F. Supp. 2d 1339, 1340 (J.P.M.L. 2012) (denying centralization of five personal injury and wrongful death actions involving alleged defects in a surgical device); *In re Abbott Labs., Inc., Similac Prods. Liab. Litig.*, 763 F. Supp. 2d 1376, 1376-77 (J.P.M.L. 2011) (denying centralization of nine actions alleging injury from recalled baby formula); *In re Blair Corp. Chenille Robe Prods. Liab. Litig.*, 703 F. Supp. 2d 1379, 1380 (J.P.M.L. 2010) (denying centralization of four personal injury and wrongful death actions); *In re Depo-Provera Prods. Liab. Litig.*, 499 F. Supp. 2d 1348, 1349 (J.P.M.L. 2007) (denying certification of oral contraceptive medical monitoring class action and two personal

[4] A copy of the current Depo-Testosterone label is attached as Exhibit B. A contraindication in a label informs a treating physician that "the risk from use clearly outweighs any possible therapeutic benefit" of the medication in the relevant population. FDA GUIDANCE FOR INDUSTRY, WARNINGS AND PRECAUTIONS, CONTRAINDICATIONS, AND BOXED WARNING SECTIONS OF LABELING FROM HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS – CONTENT AND FORMAT, at 8 (October 2011) (attached as Exhibit C).

injury actions); *accord In re Michaels Stores, Inc., Pin Pad Litig.*, 844 F. Supp. 2d 1368, 1368 (J.P.M.L. 2012) (denying transfer of seven individual consumer actions); *In re Air Crash Near Islamabad, Pak.*, 777 F. Supp. 2d 1352, 1353 (J.P.M.L. 2011); *cf. In re Professional Basketball Antitrust Litig.*, 344 F. Supp. 1405, 1407 (J.P.M.L. 1972) (denying transfer of eight cases without prejudice because centralization was premature).

As the Panel's prior decisions reflect, coordinating the cases against the Pfizer entities and other non-gel manufacturers is premature in light of the small number of cases. The Panel also has recognized the inequity of subjecting all manufacturers to an MDL where "several defendants are named in but a handful of actions" and there are significant differences between their products. *In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010). And where there are dozens of claims against one manufacturer but only a handful against other manufacturers, the Panel has granted transfer for claims against the main manufacturer but denied transfer for the rest. *See In re Aredia & Zometa Prods. Liab. Litig.*, 429 F. Supp. 2d 1371, 1372 (J.P.M.L. 2006) (granting centralization for thirty actions and denying centralization in five actions that involved different medications and manufacturers). The Panel should do the same here, at least until (if ever) there are a sufficient number of cases to warrant transfer of the Depo-Testosterone cases.

B. Depo-Testosterone Differs from Topical Gel Testosterone Therapies in Critical Respects, and Those Differences Will Unnecessarily Complicate the Management of an MDL.

In addition to being administered differently, Depo-Testosterone differs from topical gel therapies in a number of important respects, including: (1) the type and dose of testosterone that patients receive; (2) the existence of generic manufacturers who offer the same medications, such that product identification may be at issue in cases involving Depo-Testosterone; and (3) how the Pfizer entities promote the medication. These differences will make management of a litigation

that includes gel and non-gel manufacturers, particularly the Pfizer entities, much more difficult for an MDL court.

First, Depo-Testosterone uses a different type of testosterone than topical gels. The active ingredient in Depo-Testosterone is testosterone cypionate, which is an ester of testosterone that is distinct from the "pure" testosterone found in other therapies. Testosterone esters make testosterone more lipophilic (easily dissolved in fatty tissue), so the active ingredient in Depo-Testosterone is released more gradually than with topical gels.

Patients who take Depo-Testosterone also are exposed to significantly less testosterone than patients who use topical gels. Depo-Testosterone is administered in 100 mg/mL or 200 mg/mL doses by injection every two to four weeks. At the highest dose administered every two weeks, a patient who uses Depo-Testosterone would be exposed to approximately 5,200 mg of testosterone annually. By comparison, a patient who uses a topical gel is exposed to almost triple the amount of testosterone (approximately 14,600 mg to 21,900 mg) annually. Forcing the litigants and an MDL court to parse through the effects of different formulations and different doses will complicate discovery and *Daubert* proceedings relating to scientific issues, whereas an MDL limited to topical gels will be more straightforward.

Second, Depo-Testosterone no longer enjoys patent protection. As a result, a number of generic manufacturers make injectable products containing testosterone cypionate. Some plaintiffs' medical records may identify testosterone cypionate as the product they received without also identifying the manufacturer. Therefore, in Depo-Testosterone cases, the parties will have to conduct discovery regarding product identification (*i.e.*, who manufactured the injectable testosterone the plaintiff received), and the courts will have to entertain a variety of

related summary judgment motions.[5] By contrast, the gels enjoy patent protection, which means generic manufacturers are precluded from making them until the patents expire. An MDL court tasked solely with gel cases will not be faced with these product identification and related liability issues.

Third, nearly all the complaints filed to date allege that defendants engaged in "massive advertising campaigns designed to convince men that they suffered from low testosterone." *See, e.g.*, Amerson Compl. ¶ 44 (attached as Exhibit D). According to Plaintiffs' allegations, this "aggressive, award-winning" campaign consisted of direct-to-consumer television advertising and "an aggressive unbranded 'disease awareness' campaign to alert men that they might be suffering from 'low T.'" *See id.* ¶¶ 4, 59. Yet, since at least the introduction of the topical gels, the Pfizer entities have not engaged in any direct-to-consumer television or print advertisements for Depo-Testosterone or in any unbranded advertising. In light of these differences, the discovery with regard to plaintiffs' marketing claims will be very different for the Pfizer entities compared to the gel manufacturers.

In similar circumstances, where "[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)," the Panel has recognized that those distinct issues "will overwhelm the few common issues . . . [and] will add few efficiencies to the resolution of this litigation." *In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350, 1351 (J.P.M.L. 2012) (citations omitted); *see also In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d at 1377 (denying

[5] For example, where a plaintiff used a generic testosterone cypionate injection, the courts may have to entertain motions relating to whether one manufacturer can be held liable for harm caused by another manufacturer's product or whether failure-to-warn claims against generic manufacturers are preempted under *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011).

centralization where there were a "number of different pain pumps made by different manufacturers" which came in "different sizes and designs, with differing volume, duration, and flow capacities"). Indeed, for those very reasons, the Panel is "typically hesitant to centralize litigation against multiple, competing defendants which marketed, manufactured and sold similar products." *In re Yellow Brass Plumbing Component Prods. Liab. Litig.*, 844 F. Supp. 2d 1377, 1378 (J.P.M.L. 2012). The Panel should be similarly cautious here, and it should not complicate an MDL focused on topical gel therapies by including all testosterone therapies.

C. For the Cases Involving Both AndroGel and Depo-Testosterone Use, the Panel Should Sever and Transfer the AndroGel Claims to an MDL and Leave the Claims against the Pfizer Entities in Their Present Districts.

The parties that have requested transfer of all testosterone therapy cases have done so in part on the basis of mixed-use cases in which plaintiffs took more than one testosterone therapy. In light of the significant differences between the gel therapies and Depo-Testosterone, the difficulties presented in managing gel therapy and Depo-Testosterone cases together, and the very small number of cases involving gel therapies and Depo-Testosterone, the Panel should limit any MDL proceeding to topical gel therapies only. The cases currently pending solely against the Pfizer entities and other non-gel manufacturers—four cases total—could remain pending in their present districts.

For the four mixed-use cases that involve plaintiffs who used AndroGel as well as a non-gel therapy, the Panel should sever the AndroGel claims against AbbVie and Abbott and transfer those claims to the topical gel MDL for pretrial proceedings, a tool the Panel has used previously for the ease of judicial management. *See, e.g.*, *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005) (severing cases that involved two different medications and holding that "claims involving a prescription drug other than Vioxx . . . do not share sufficient questions of fact with claims relating to Vioxx to warrant inclusion of these non-Vioxx claims in MDL-

1657 proceedings"). The remaining claims against the Pfizer entities (and perhaps other non-gel manufacturers, who also have opposed transfer) could remain in their present districts. After the conclusion of pretrial proceedings in the gel MDL, the MDL court will be in the best position to determine whether (and, if so, when) to remand the mixed-use cases to their transferor districts. In the alternative, if the Panel believes severance is not warranted, it could transfer the mixed-use cases to the MDL, where presumably the MDL court will focus discovery on the vast majority of claims that involve gel therapies rather than the small number that also involve use of a non-gel therapy.

CONCLUSION

For the foregoing reasons, Defendants Pfizer and Pharmacia & Upjohn respectfully request that the Panel deny the motions of certain Plaintiffs—and the requests of certain Defendants—to transfer for coordinated pretrial proceedings the cases involving Depo-Testosterone. For the two cases in which AbbVie and Abbott are named as co-defendants along with the Pfizer entities, the Pfizer entities request that the Panel sever the claims against Abbott and AbbVie and transfer them to an MDL focused on topical gels, while leaving the claims against the Pfizer entities pending in their present districts.

Respectfully submitted,

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