BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE:
ANDROGEL PRODUCT LIABILITY LITIGATION

MDL DOCKET NO. _____

BRIEF IN SUPPORT OF TRANSFER, COORDINATION, AND/OR CONSOLIDATION PURSUANT TO 28 U.S.C. § 1407

Pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Movants[1] respectfully request that the Judicial Panel on Multidistrict Litigation (the "Panel") enter an order consolidating and transferring all AndroGel actions to the Northern District of Illinois, Eastern Division, for coordinated or consolidated pretrial proceedings.

I. BACKGROUND

A. AndroGel

AndroGel is a testosterone replacement therapy designed, manufactured, supplied, marketed, promoted and/or sold by Abbott Laboratories, Inc. and AbbVie Inc. (the "AbbVie

[1] Movants are the Plaintiffs in the following cases: *William Blades, et al. v. AbbVie Inc., et al.*, 1:14-cv-1471 (N.D. Ill.); *Gary Carpenter, et al. v. AbbVie Inc., et al.*, 1:14-cv-1472 (N.D. Ill.); *Robert Cripe v. AbbVie Inc., et al.*, 1:14-cv-843 (N.D. Ill.); *Thomas Dobbs v. AbbVie Inc., et al.*, 1:14-cv-1474 (N.D. Ill.); *Roger Gibby, et al. v. AbbVie Inc., et al.*, 1:14-cv-917; *Michael Gordon, et al. v. AbbVie Inc., et al.*, 1:14-cv-1478 (N.D. Ill.); *Joseph Hardee, et al. v. AbbVie Inc., et al.*, 1:14-cv-918 (N.D. Ill.); *Thomas Headley v. AbbVie Inc., et al.*, 1:14-cv-1475 (N.D. Ill.); *Christopher Hughes, et al. v. AbbVie Inc., et al.*, 1:14-cv-1476 (N.D. Ill.); *Buddy Humphries, et al. v. AbbVie Inc., et al.*, 1:14-cv-1473 (N.D. Ill.); *William Jackson, et al. v. AbbVie Inc., et al.*, 1:14-cv-1477 (N.D. Ill.); *Joseph Jones, et al. v. AbbVie Inc., et al.*, 1:14-cv-1479 (N.D. Ill.); *Mark King, et al. v. AbbVie Inc., et al.*, 1:14-cv-1480 (N.D. Ill.); *Calvin Lewis, et al. v. AbbVie, Inc., et al.*, 1:15-cv-1480 (N.D. Ill.); *Robert Saylor, et al., v. AbbVie Inc., et al.*, 1:14-cv-1482 (N.D. Ill).

Defendants").[2] AndroGel is indicated for use in treating conditions associated with hypogonadism, a specific condition of the sex glands. Hypogonadism is a specific and recognized condition of the endocrine system which involves severely diminished production or nonproduction of testosterone. AndroGel is not approved for ordinary age-related declines in testosterone levels.

The AbbVie Defendants orchestrated national disease awareness campaigns designed to educate men about the symptoms of low testosterone levels or "Low T," which include listlessness, increased body fat, and moodiness, all of which are more commonly a result of aging, weight gain or lifestyle rather than low testosterone levels. Testosterone sales have more than doubled since 2006 and are expected to triple to $5 billion by 2017.[3]

The combined effect of these ad campaigns has been to create the belief in consumers and physicians that low testosterone affects a large number of men in the United States and that AndroGel is a safe drug that gives numerous health benefits with minimal risks. These impressions are wrong. A study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001 - 2011" indicated that many men who get Testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed Testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a Testosterone prescription.

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[2] Testosterone is available in several different forms, including gels, injections and patches. Examples of some of other Testosterone drugs prescribed in the United States are: Axiron, Androderm, Testim, Fortesta, Delatestryl and Striant.

[3] Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg Businessweek, *available at:* http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

More importantly, AndroGel is not safe. Multiple medical studies indicate that Testosterone use in men can cause serious health problems, including heart attack, stroke, pulmonary embolism, deep vein thrombosis and thromboembolic events. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the Testosterone group suffered adverse events. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" which indicated that Testosterone therapy raised the risk of death, heart attack and stroke by about 30%. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that Testosterone use doubled the risk of heart attacks in men over sixty five years old and tripled the risk in men younger than sixty five with a previous diagnosis of heart disease.

On January 31, 2013, the U.S. Food and Drug Administration announced that it was re-evaluating its opinion on the safety of Testosterone in light of the recent studies and numerous reports of injuries. Despite this existing body of literature and numerous complaints of injuries to the AbbVie Defendants and the FDA, the AbbVie Defendants have never included risks of cardiovascular injuries. The AbbVie Defendants continue to market and promote AndroGel without conducting any additional safety testing or issuing additional warnings.

B. AndroGel Litigation

As of March 28, 2014, thirty-eight (38) AndroGel cases have been filed in three (3) United State District Courts: thirty-three (36) actions are currently pending before Judge

Matthew F. Kennelly in the Northern District of Illinois or will shortly be re-assigned to him, one (1) action is pending in the Eastern District of Pennsylvania, and one (10 action is pending in the District of Colorado.[4] *See* attached Schedule of Actions. Each action asserts substantially similar claims and seeks substantially similar relief. In each action, plaintiffs allege, inter alia, that the AbbVie Defendants manufactured, marketed, distributed, supplied, promoted, and/or sold AndroGel, which is defective and unreasonably dangerous in that it causes heart attack, stroke, pulmonary embolism, deep vein thrombosis and thromboembolic events; that the AbbVie Defendants knew or should have known of the risk of injuries associated with AndroGel; that the AbbVie Defendants marketed, distributed, and/or sold AndroGel without adequate warnings concerning its risks; and that as a direct and proximate result of use of AndroGel, Movants suffered serious injuries, physical and mental pain and suffering, as well as economic loss.

Given the widespread use of AndroGel for over a decade and that the first action was only filed on February 4, 2014, Movants expect that the number of cases will rapidly expand.

II. ARGUMENT

A. These Actions are Appropriate for Transfer and Pretrial Coordination under 28 U.S.C. §1407

Title 28 U.S.C. §1407(a) of the United States Code provides "when civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings." 28 U.S.C. §1407(a). The Panel "shall" make such transfers when in furtherance of the "convenience of the parties and witnesses" and when transfer will "promote the just and efficient conduct of

[4] One AndroGel case has also been filed in the Court of Common Pleas of Philadelphia County. *See Olivetti v. Auxilium Pharmaceuticals, Inc. et al.*, Case No. 140303508 (Philadelphia Ct. Common Pleas).

the actions." *Id.* Pharmaceutical product liability cases are particularly well-suited for coordination because they involve common questions of fact concerning the "development, testing, manufacturing and marketing" of the products. *See, e.g., In re Accutane Prods. Liab. Litig.*, 343 F. Supp. 2d 1382, 1383 (JPML 2004); *In re Trasylol Prods. Liab. Litig.*, 545 F. Supp. 2d 1357, 1358 (JPML 2008) (common questions regarding the safety profile of a drug and the manufacturer's warnings); *In re Vytorin / Zetia Mktg., Sales Practices & Prods. Liab. Litig.*, 543 F. Supp. 2d 1378, 1380 (JMPL 2008) (common questions regarding the use and/or marketing of two pharmaceutical drugs). Because of the number of current and anticipated AndroGel actions and the existence of common questions of fact, the requirements for transfer under §1407 are met here.

The currently pending AndroGel actions involve common questions of fact, including whether the AbbVie Defendants knew or should have known of the dangerous propensity of the product to cause heart attack, stroke, pulmonary embolism, deep vein thrombosis and thromboembolic events; whether the warnings were sufficient to alert users of the risk of adverse events; whether the AbbVie Defendants were negligent in marketing, promoting or distributing the product; and whether the product conformed to the AbbVie Defendants' implied warranties. *See* Ex. 1, Defendants' Response to Plaintiff's Motion to Coordinate Actions, *Marino v. AbbVie, Civil Case No. 1:14-cv-777,* Doc. 22, 2 (N.D. Ill. Mar. 3, 2014) ("Defendants AbbVie and Abbott Laboratories **agree that all of the recently filed cases alleging personal injuries from the use of AndroGel®…are related**.") (emphasis added). According to the AbbVie Defendants, plaintiffs' actions are "essentially photocopies of each other, **assert nearly identical facts, causes of action, and claims for relief**." *Id.* (emphasis added).

Thirty-eight (38) AndroGel actions have already been filed in three (3) federal court jurisdictions. These cases alone would justify centralization, as the Panel routinely coordinates cases involving significantly fewer actions in two districts.[5] Due to the widespread prescribing and use of AndroGel and current client inventories, Movants' Counsel anticipate thousands of cases will be filed in state and federal courts across the country. *See In re Camp Lejeune, N.C. Water Contamination Litig.*, 763 F. Supp. 2d 1381, 1382 (J.P.M.L. 2011) (considering the potential for "a large number of additional related actions to be filed"); *In re Footlocker, Inc., Fair Labor Standards Act (FLSA) & Wage & Hour Litig.*, MDL No. 2235, 787 F. Supp. 2d 1364, 2011 WL 2118980, at *1 (J.P.M.L. 2011) (stating that "[t]hough a large number of actions are not presently before the Panel, also weighing in favor of centralization is that additional related actions alleging similar class claims in other states could well be filed."). Consequently, there is a definite need for centralized coordination of these actions to avoid overlapping discovery and conflicting pretrial rulings. Judicial economy can only truly be achieved through this Panel's formal consolidation of all AndroGel actions in issue.[6]

The number of Plaintiffs' counsel involved also continues to expand. Coordinated treatment is needed to ensure uniformity in discovery rulings and to avoid duplicative discovery

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[5] The Panel only requires two actions pending in two federal districts for consolidation under 28 U.S.C. § 1407. *See E.g., In re Toys "R" Us-Del., Inc., Fair Accurate Credit Transactions Act (FACTA) Litig.*, 581 F. Supp. 2d 1377, 1377 – 78 (JPML 2008) (Consolidating two actions pending in two districts); *In re Glaceaus Vitamin Water*, 764 F. Supp. 2d at 1350 (involving three actions in three districts); *In re Porsche Cars N. Am., Ic. Plastic Coolant Tubes Prods. Liab. Itig.*, 787 F. Supp. 2d 1359, 1360 (JPML 2011) (involving four actions in four districts); *In re Se. Milk Antitrust Litig.*, 530 F. Supp. 2d 1359, 1360 (JPML 2008) (involving four actions in two districts); *In re Camp Lejeune, N.C. Water Contamination Litig.*, 763 F. Supp. 2d 1381, 1381-82 (JPML 2011) (involving four actions in four districts); *In re Enfamil Lipil Mktg. & Sales Practices Litig.*, 764 F. Supp. 2d 1356, 1357 (JPML 2011) (involving six actions in six districts).

[6] Plaintiffs are not opposed to centralization of cases involving other testosterone replacement therapy defendants should that become appropriate at some point in the future.

efforts. The Panel routinely centralizes cases in order to avoiding conflicting decisions and inconsistent rulings. *See generally In re Brown Co. Sec. Lit.*, 325 F. Supp. 307, 308 (JPML 1971) (noting that transfers are practically compelled so as to avoid overlapping or inconsistent class action rulings); *In re Career Acad. Antitrust Lit.*, 57 F.R.D. 569, 571 (E.D. Wis. 1972); *In re Pharmacy Benefit Managers Antitrust Lit.*, 425 F. Supp. 2d 1352, 1353 (JPML 2006) (noting that centralization is desirable to avoid duplicative discovery and to prevent inconsistent or repetitive pretrial rulings).

Finally, the convenience of the parties and witnesses clearly supports transfer and pretrial consolidation. This Panel routinely recognizes that centralizing mass tort pharmaceutical litigation in one court benefits *both* plaintiffs and defendants. Specifically, consolidation strikes a balance between allowing the defendant to conduct discovery only once, and entitling the plaintiff to coordinate their efforts and share their work with other plaintiffs. *In re: Janus Mutual Funds* at 1361. Recognizing the soundness of this policy, this Court in *In re: Bladwin-United Corp. Litigation*, 581 F. Supp. 739 (MDL 1984) noted, "[I]t is most logical to assume that prudent counsel will combine their forces and apportion the workload in order to streamline the efforts of the parties and witnesses, their counsel and the judiciary, thereby effectuating an overall savings of cost and a minimum of inconvenience to all concerned. *Id.* At 741 (citing *In re: Nissan Motor Corp. Antitrust Litig.*, 385 F. Supp. 1253, 1255 (MDL 1974)). Centralizing these actions will save both sides (and the Court) countless resources by streamlining the litigation in one forum. Because of the common defendants, identical issues of law and fact, the number of current claims, and the expected rapid expansion of claims, transfer and consolidation is most convenient for the parties and potential witness common to these actions.

B. The Northern District of Illinois is the Appropriate Forum for this Litigation

The factors considered by this Panel in determining the appropriate MDL forum include: (1) the location of the parties, witnesses and documents; (2) the accessibility of the proposed transferee district to parties and witnesses; and (3) the respective caseloads of the proposed transferee district courts. *See In re Corn Derivatives Antitrust Litig.*, 486 F.Supp. 929, 93 1-32 (J.P.M.L. 1980). Analysis of each of these factors supports transfer of these actions to the Northern District of Illinois for consolidated pretrial proceedings.

The United States District Court for the Northern District of Illinois is an appropriate forum for transfer, coordination and/or consolidation because it is the district in which the most actions have been filed. Because of the large number of AndroGel cases that are likely to be filed, it is anticipated that the AndroGel litigation will require a substantial amount of judicial time and energy. As such, the judicial efficiency and just resolution of these actions is best served by transferring these actions to one skilled jurist in a forum with a light MDL case load. Movants are confident that Judge Matthew F. Kennelly in the Northern District of Illinois will promote the goal of a just resolution in this MDL as speedily, inexpensively, and fairly as possible. Thirty-six (36) of the thirty-eight (38) AndroGel actions currently filed, and all of the Northern District of Illinois AndroGel actions, have been or will shortly be reassigned to Judge Kennelly for consolidation. Ex. 2, Consolidation Order, *Marino v. AbbVie, Civil Case No. 1:14-cv-843*, Doc. 22, 2 (N.D. Ill. Mar. 3, 2014). In addition to his familiarity with these proceedings, Judge Kennelly would be an ideal choice to oversee this MDL because he is an experienced member of the Court with over fifteen (15) years of experience as a federal judge. Judge Kennelly has a tremendous reputation for his legal acumen and efficient docket. Further, Judge Kennelly has previous MDL experience. Judge Kennelly is currently presiding over two small MDLs. The first is MDL 1997 *In Re: Text Messaging Antitrust Litigation* with only three (3)

pending cases. The second is MDL 2372 *In Re: Watson Fentanyl Patch Products Liability Litigation* with only twenty-five (25) pending cases. Thus, Judge Kennelly has the necessary resources, skill and experience to devote the substantial time and effort to pretrial matters that this complex docket is likely to require.

The Northern District of Illinois is most accessible location for the parties and witnesses. Chicago, Illinois is not only geographically located near the center of the country, it is also the location of the principal places of business for Defendants AbbVie Inc. and Abbott Laboratories, Inc. The United States District Court is only eighteen (18) miles from Chicago O'Hare International Airport, which serves all major cities with approximately 1,036 daily direct flights to 140 U.S. cities. Chicago has a public transportation system and numerous hotels and conference facilities are closely situated to the courthouse.

Finally, the caseload of the Northern District of Illinois supports transfer to this district. Data from the Federal Court Management Statistics reveals the Northern District of Illinois is well-suited to provide an efficient disposition of these cases. According to judicial statistics for the twelve-month period ending in March 31, 2013, civil cases proceeded to trial in the Northern District of Illinois in 33.7 months. The median time for filing to disposition other than trial for civil cases was only 6.6 months.

The Northern District of Illinois, and the Eastern Division in particular, is an appropriate and logical choice for consolidated pretrial proceedings in this litigation.

III. CONCLUSION

Transfer and consolidation for pretrial proceedings of all pending and subsequently filed AndroGel actions will promote the just and efficient conduct of these actions by allowing national coordination of discovery and other pretrial efforts, will prevent duplicative and

potentially conflicting pretrial rulings, will reduce the costs of litigation and allow cases to proceed more efficiently to trial. For the foregoing reasons, Movants respectfully request that the Panel enter an order that the related actions be consolidated and transferred to the United States District Court for the Northern District of Illinois, Eastern Division.

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Respectfully Submitted,

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