

November 2, 2015

<u>Via Email and FedEx</u>

Hon. Matthew F. Kennelly United States District Judge United States District Court for the Northern District of Illinois Everett McKinley Dirksen United States Courthouse 219 South Dearborn Street Chicago, IL 60604

Re: In re Testosterone Replacement Therapy Prods. Liab. Litig., Case No. 1:14-CV-01748 MDL 2545

Dear Judge Kennelly:

Pursuant to Section I.B of Amended CMO No. 14 (Dkt. No. 793), the Plaintiffs' Steering Committee (the "PSC") identifies the 16 cases listed below for inclusion in the pool of 32 cases that will proceed to case-specific core discovery, for purposes of identifying the first trial cases in this litigation. Based on the PSC's early review of the information available for the bellwether-eligible pool, the PSC respectfully submits that the below cases implicate a number of general issues and considerations that could inform the Court and the parties regarding common issues in this litigation. In accordance with Amended CMO No. 14, eight of the cases involve clotting injuries and eight involve cardiovascular injuries.

Plaintiffs in this MDL contend that AndroGel, marketed by Defendants AbbVie Inc., Abbott Laboratories, and their predecessors (collectively, "AbbVie"), is a substantial factor in the development of the thromboembolic and cardiovascular events alleged herein, including deep vein thrombosis ("DVT"), pulmonary embolism ("PE"), myocardial infarction ("MI"), and stroke. By virtue of a massive and aggressive marketing campaign, Plaintiffs' maintain that AbbVie sought to—and did—expand the use and resulting sales of AndroGel well beyond its approved use en route to blockbuster status. To do so, AbbVie promoted AndroGel for use in a broad range of conditions for which benefit had never been demonstrated. Plaintiffs anticipate that the marketing of AndroGel for unproven benefits, and the resulting exposure by Plaintiffs to the drug and all of its risks, will be a focus in the bellwether cases.

As the Court is aware, these 16 cases were selected from a pool of 100 randomly-selected cases that met certain eligibility criteria, namely: (i) the plaintiffs in these cases served a completed Plaintiffs' Fact Sheet by June 15, 2015; (ii) named only AbbVie as a defendant; and (iii) agreed to relinquish their right to trial in their venue of original filing (or other venue)

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should their case be selected for one of the first six trials (as may be appropriate under *Lexecon*). At the status conference on October 15, 2015, the Court directed the PSC to pick 16 cases and AbbVie to pick 16 cases to create the discovery pool of 32 cases. The PSC understands that any objections by the parties to each other's proposed cases are due on or before November 9, 2015 (although the parties originally agreed to a November 8 deadline, that date was selected in error because it falls on a Sunday).

Among the pool of 100 randomly-selected cases, approximately two-thirds of Plaintiffs alleged a cardiovascular injury, with the majority of the cardiovascular cases being heart attacks and the remainder strokes or other cardiac/arterial events. Approximately 37 of the cases allege thromboembolic clotting events, generally manifesting as either (or combinations of) DVT, PE or other venous clots. Plaintiffs in the bellwether-eligible cases, were, on average, in their mid-50s when they suffered their injury, with the vast majority of these plaintiffs suffering their injuries in 2010 or later. Relevant to AbbVie's interactions with physicians in the pool, of the 100 bellwether eligible plaintiffs, AbbVie made payments to the prescribing physician in nearly two-thirds of the cases, and approximately three-quarters of the prescribing physicians were detailed by AbbVie sales representatives.¹

Based on its review of general information for the 100 bellwether-eligible cases, the PSC believes that the following eight thromboembolism cases and eight cardiovascular cases reasonably reflect the issues and facts in the case pool, and should appropriately proceed into core discovery to further develop these cases for the Court's ultimate selection of bellwether trial cases.

I. Background on Type of Injury

A. Thromboembolism ("TE")

As background, the cases involving a TE concern primarily an embolus or blood clot in a vein, with the majority of the cases involving clots that appear as a PE or DVT. A PE usually arises when a blood clot originating in the venous system travels to the lungs. After traveling to the lung, the clot can lodge at the bifurcation of the main pulmonary artery, which compromises the blood flow to the heart. This can lead to hypoxia and death. Smaller clots typically travel more distally, occluding smaller vessels in the lung periphery. These are more likely to produce pleuritic chest pain. Most pulmonary emboli are multiple, and the lower lobes of the lungs are involved more commonly than the upper lobes of the lungs. Other sources of the emboli

¹ As the Court is aware, the PSC requested additional discovery before selecting these 16 cases (such as AbbVie's Field Contact Reports that describe the activity of sales representatives, including interactions between sales representatives and doctors), and that the Court has agreed that these materials will be relevant for case-specific discovery but did not compel production before these 16 cases are selected. The information included in the Defendants' Fact Sheets confirmed that sales calls on doctors (so-called "detailing") and direct-to-consumer advertising will likely affect ultimate trial selection.

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(although less common) are the iliac veins, renal veins, or upper extremity veins. A PE is a potentially lethal condition.

A DVT is blood clot that occurs in a deep vein. It typically presents with extreme pain and is usually diagnosed by doppler or other imaging tests. The course of treatment is hospitalization with blood thinner medication utilized for typical three to nine months, and at times a lifetime regiment is required. Additional treatment options can include surgical intervention, placement of a filter (to prevent further/future clotting), and even compression stockings in the affected leg.

The consequences of a blood clot depend largely on where it occurs, but they can be relatively limited or they can be severe. Follow-up treatments can include blood thinning medications, compression stockings and general limitations designed to minimize the development of a hypercoagulable state. Further, after a person suffers a clotting event, he or she is at an increased risk of another.

B. Cardiovascular Injury

The cases involving cardiovascular injury include both myocardial infarctions (heart attacks) and strokes. Heart attacks and strokes are usually acute events and are mainly caused by a blockage that prevents blood from flowing to the heart or brain. The diagnosis of either a heart attack or stroke occurs during hospitalization and typically in an emergency room setting with a variety of different diagnostic and clinical tests. The resulting damage from a heart attack can vary widely, both in terms of permanency and rehabilitation. Likewise, the neurological and other damages from a stroke can vary widely as well.

The consequences of a heart attack include: cardiac damage, long term medications and doctor visits, limits on activities of daily living, and more. The consequences a stroke include neurological impairment, including vision loss, speech and language disturbances and/or loss, memory loss (short/long term), fine and gross motor skill damages, and more. Lastly, having such an event (heart attack or stroke) increases one's likelihood of having another of these events in the future.

II. Bellwether Candidate Case Summaries

A. Eight Clotting Injury Cases (in alphabetical order):

1. *Lance Blanck*, No. 1:15-cv-01077: Lance Blanck is a 61 year-old resident of South Lake Tahoe, California, who was 59 years old at the time of his injury. Mr. Blanck used AndroGel approximately in 2013. In or about December 2013, he suffered a PE and DVT, with a resulting hospital stay. Before his hospitalization, Mr. Blanck noted swelling in his right calf, which got progressively worse over the course of several days. Mr. Blanck is represented by Mark Hoffman, Esq. of Ross Feller Casey, LLP.

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- 2. *Robert Cripe*, No. 1:14-cv-00843: Robert Cripe is a 47 year-old resident of Overland Park, Kansas, who was 42 years old at the time of his injury. Mr. Cripe used AndroGel approximately in 2011 for a relatively short period of time before his injury. Mr. Cripe began experiencing numbness in his right foot, hip and abdomen in or about February 2011. He was hospitalized and after extensive diagnostic testing, he was diagnosed with a spinal cord infarction caused by a blood clot. Mr. Cripe is represented by Ronald E. Johnson, Jr., Esq. of Schachter, Hendy & Johnson.
- 3. *Michael Ennis*, No. 1:15-cv-00624: Michael Ennis is a 67 year-old resident of Oakland, California, and was 58 years old at the time of his first injury. Mr. Ennis used AndroGel approximately in 2007. In 2007 a right calf DVT was diagnosed, and in 2008 Mr. Ennis suffered a PE, for which he was hospitalized. Mr. Ennis is represented by Christopher A. Seeger, Esq. of Seeger Weiss LLP.
- 4. *William Ferrer*, No. 1:15-cv-00345: William Ferrer is a 65 year-old resident of Cordova, Tennessee, who was 63 at the time of his injury. Mr. Ferrer used AndroGel approximately from 2009 to 2014. In or about March 2014, he suffered a PE and DVT. As a result of his TRT-related injuries, he was hospitalized. Mr. Ferrer is represented by Timothy Becker, Esq. of Johnson Becker PLLC.
- Jeffrey Friedel, No. 1:14-cv-06152: Jeffrey Friedel is a 58 year-old resident of San Tan Valley, Arizona. Mr. Friedel used AndroGel approximately in 2012. Mr. Friedel suffered a PE and DVT in or about August 2012, and he suffered another PE in or about November 2013. Mr. Friedel was hospitalized for both injuries. Mr. Friedel is represented by Ronald E. Johnson, Jr., Esq. of Schachter, Hendy & Johnson.
- 6. *Arthur Myers*, No. 1:15-cv-01085: Arthur Myers is a 50 year-old resident of Prescott Valley, Arizona. Mr. Myers used AndroGel approximately in 2003 to 2008. In or about February 2008 Mr. Myers suffered a PE. Mr. Myers is represented by Mark Hoffman, Esq. of Ross Feller Casey, LLP.
- Jesse Patridge, No. 1:14-cv-07960: Jesse Patridge is a 74 year-old resident of Cynthiana, Kentucky. Mr. Patridge used AndroGel approximately in 2010 to 2011. In or about January 2011, he suffered a right calf DVT, which required hospitalization. Mr. Patridge is represented by Trent Miracle, Esq. of Simmons Hanly Conroy LLC.
- Michael Romanik, No. 1:14-cv-08202: Michael Romanik is a 50 year old resident of Millville, New Jersey. Mr. Romanik used AndroGel approximately in 2011 and 2012. Mr. Romanik suffered a PE in or about April 2012, which required hospitalization. Mr. Romanik is represented by Mark Hoffman, Esq. of Ross Feller Casey, LLP.

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B. Eight Cardiovascular Injury Cases (in alphabetical order):

- David Deel, No. 1:14-cv-10435: David Deel is a 55 year-old resident of Lancaster, Kentucky. Mr. Deel used AndroGel approximately in 2009 to 2013. In or about January 2014, Mr. Deel suffered a myocardial infarction. Mr. Deel is represented by Frank Petosa, Esq. of Morgan & Morgan, P.A.
- 2. *Gene Dial*, No. 1:15-cv-02190: This case is brought by Corliss Dial on behalf of the estate of Gene Dial. Gene Dial used AndroGel approximately in 2012 and 2013. He died at the age of 58 as a result of cardiopulmonary arrest and an acute myocardial infarction on March 15, 2013. At the time of his death, Mr. Corliss was a resident of Heaters, West Virginia. Ms. Dial is represented by Gregory S. Spizer, Esq. of Anapol Weiss.
- 3. *Michael Guy*, No. 1:14-cv-08894: Michael Guy is a 64 year-old resident of Salem, Alabama. Mr. Guy used AndroGel approximately in 2010 to 2013. In or about November 2013, Mr. Guy suffered a stroke. Mr. Guy is represented by Christopher T. Kirchmer, Esq. of Provost Umphrey Law Firm L.L.P.
- 4. *Jeffrey Konrad*, No. 1:15-cv-00966: Jeffrey Konrad is a 54 year-old resident of Collierville, Tennessee. Mr. Konrad used AndroGel approximately in 2010. In or about July 2010, he suffered a myocardial infarction at the age of 49. Mr. Konrad is represented by Matthew Teague, Esq. of Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
- Anthony Long, No. 1:14-cv-06996: Anthony Long is a 58 year old resident of Hendersonville, Tennessee. Mr. Long used AndroGel approximately in 2011 to 2014. In or about December 2013, Mr. Long suffered a stroke. Mr. Long is represented by Scott Levensten, Esq. of the Levensten Law Firm.
- Jesse Mitchell, No. 1:14-cv-09178: Jesse Mitchell is a 52 year-old resident of Portland, Oregon. Mr. Mitchell used AndroGel approximately in 2007 to 2012. In or about November 2012, Mr. Mitchell suffered a myocardial infarction. Mr. Mitchell is represented by David J. Diamond, Esq. of Goldberg & Osborne.
- Mark Staton, No. 1:15-cv-00619: Mark Staton is a 53 year-old resident of Medina, Tennessee. Mr. Staton used AndroGel approximately in 2012 to 2014. He suffered a stroke in an artery that supplies the optic nerve, which was diagnosed in or about February 2013. Mr. Staton is represented by Stephen T. Blackburn, Esq. of Baron & Budd, P.C.
- 8. *Dave White*, No. 1:14-cv-03818: This case is brought by Dave White's widow, Peggy White, on behalf of his estate and his three children, following Mr. White's death on September 9, 2013 at the age of 60. Mr. White used AndroGel approximately in 2012 and 2013. Mr. White suffered a myocardial infarction in or

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about September 2013. At the time of his death, Mr. White was a resident of Fulton, Maryland visiting Las Vegas, Nevada. Ms. White is represented by Robert K. Jenner, Esq. of Matthews & Associates.

Plaintiffs are prepared to discuss the cases listed above, or any other aspect of the bellwether process, at any time that is convenient for the Court.

Respectfully submitted,

Christopher A Seeger

Plaintiffs' Co-Lead Counsel

cc: David Bernick (by email and U.S. mail) Hope S. Freiwald (by email and U.S. mail) Michelle Yeary (by email and U.S. mail) Andrew K. Solow (by email and U.S. mail) Pamela J. Yates (by email and U.S. mail) David E. Stanley (by email and U.S. mail) Janet H. Kwuon (by email and U.S. mail) Matthew A. Holian (by email and U.S. mail) Loren Brown (by email and U.S. mail) Joseph P. Thomas (by email and U.S. mail)