UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	**CASE NO. 1:14-CV-01748**
	MDL 2545
This Document Relates to:	
All Actions	**HON. MATTHEW F. KENNELLY**

JOINT SUBMISSION REGARDING
ABBVIE-ONLY BELLWETHER TRIAL SEQUENCE

Pursuant to the Court's request at the February 16, 2017 Case Management Conference ("CMC"), the parties jointly submit the following summaries of the seven AbbVie-only bellwether trial cases (in alphabetical order, by injury type) and the parties' respective proposals for determining the order in which the cases will be tried.[1]

I. Summaries of Bellwether Trial Cases

A. CV Cases

1. **Edward Cribbs** (Case No. 15-cv-01056)

(a) Background

(i) Alleged injury: Heart attack

(ii) Date of alleged injury: May 25, 2012

(iii) Approximate dates of alleged AndroGel use: March 2010 – April 2014

(iv) Date of birth: October 28, 1950 (current age: 66; age at injury: 61; age at first prescription: 59)

[1] On July 25, 2016, the parties simultaneously submitted briefs to the Court (Doc. No.1406; Doc. No. 1407) as part of the bellwether selection process. These briefs set forth more detailed descriptions of the cases, including the injuries claimed by the plaintiffs.

(v) State of residence: North Carolina

(b) Plaintiffs' Additional Points of Interest

The *Cribbs* case has prominent characteristics that make this case distinctive, both factually and legally, and thus less representative of the broader collective of AbbVie-only cases. As a result, and as described below, these characteristics should direct trial of the *Cribbs* case late in the bellwether trial process (as among the seven trial candidates, the PSC proposes that this case be sequenced in the sixth trial slot). As is characteristic with several of the defense-selected bellwether cases, Mr. Cribbs has an accumulation of significant case-specific medical issues independent of the injury at issue. Beyond more general risk factors present more broadly in the AbbVie cases, such as hypertension, high cholesterol, and smoking history, Mr. Cribbs also has a medical history notable for cancer, partial nephrectomy, stroke/transient ischemic attacks, and diabetes. The PSC's experience in other pharmaceutical litigation is that substantial case-specific co-morbidities and prior medical events like those present in Mr. Cribbs' case become a dominant focus of the case-specific proofs at trial at the expense of the injury and drug at issue, and thus limit broad case-specific teachings from a trial result. On the legal side, because Mr. Cribbs is a resident of North Carolina, the measure of AndroGel warnings adequacy for the jury is likely to be from the perspective of the consumer, based on the consumer warnings, and not from that of the learned intermediary (Mr. Cribbs' prescribing physician) based on the physician prescribing information. Under a unique provision of North Carolina's products liability law, the presence of FDA-directed consumer warnings/instructions—as is the case with AndroGel and its accompanying Medication Guide—renders inapplicable the learned intermediary doctrine. *See* N.C. Gen. Stat. § 99B-5(c) (exception to the learned intermediary doctrine in prescription drug cases where consumer warnings/instructions accompany the prescription drug). Finally, North Carolina's continued

maintenance of pure contributory negligence—it is one of only five U.S. jurisdictions that continue to recognize the doctrine (Alabama, D.C., Maryland, and Virginia are the others)—further foreshadows that non-generalizable individual and unique liability and causation proofs will dominate the *Cribbs* trial.

(c) AbbVie's Additional Points of Interest

AbbVie's comments here[2] focus on whether and to what extent each case reflects cross-cutting issues of causation and failure to warn. With respect to cross-cutting causation issues, Mr. Cribbs allegedly was a long-term user of AndroGel (> 2 years before injury), who was under the age of 65 and had a history of CV risk factors at the time of his heart attack. With respect to cross-cutting failure to warn issues, Mr. Cribbs was prescribed AndroGel beginning before the first study reporting an association with CV risk was published on June 30, 2010 (i.e., the "Basaria RCT"). Mr. Cribbs' heart attack occurred after that date but before further studies reported an association of TRT with CV risk in 2013-14.

[2] As reflected below, AbbVie's preferred approach would be to determine the order of trial using a standard randomizing program. This would obviate the need for further analysis of the 7 cases.

2. Cecile Frost (Case No. 15-cv-01484)

(a) Background

(i) Alleged injury: Stroke

(ii) Date of alleged injury: February 21, 2013

(iii) Approximate dates of alleged AndroGel use: January 2012 – February 2013

(iv) Date of birth: February 23, 1953 (current age: 64; age at injury: 59; age at first prescription: 58)

(v) State of residence: California

(b) Plaintiffs' Additional Points of Interest

Now that discovery is complete and expert disclosures have been tendered, it is clear that the *Frost* case presents a substantial dispute among the parties, and thus a clear trial issue, concerning whether Mr. Frost was using AndroGel proximate to his injury.[3] In a pharmaceutical products liability case, scarcely any issue presents a greater probability of limiting the utility of a bellwether trial result than a material dispute on whether the plaintiff was using the subject drug, or was sufficiently using it, proximate to the injury. Usage questions present a substantial risk of undermining bellwether case-specific causation determinations, which are a primary case-specific takeaway from a bellwether trial. As a result, the PSC proposes that the *Frost* case be the last of the seven cases in the trial sequence. Beyond the usage issue, the defense-selected *Frost* case presents a broad range of case-specific social issues, including a history of bipolar disorder, alcohol abuse, alcohol-induced chronic pancreatitis, alcohol-related legal problems, a history of alleged domestic abuse, and admitted marijuana use in recent years contemporaneous to AndroGel use.

[3] Although Mr. Frost testified that he was using the AndroGel product at the time of injury, AbbVie's experts, relying on medical and pharmacy records, maintain that there is no documented medical evidence of such, and that Mr. Frost was off the drug for a substantial period of time prior to his CV event. *See, e.g.*, Report of Dr. William French at 16-17 (Dec. 7, 2016).

Plaintiff's history of addiction, and criminal record, are not clearly representative of the larger pool of cases and are collateral to issues of general proofs. In expert reports, AbbVie contends that Mr. Frost's alcohol use is an alternative cause of his injury, and there will be attempts to couch this social issue as a medical risk factor. *See, e.g.,* Report of Howard S. Kirshner, M.D. at 15 (Dec. 6, 2016) ("Alcohol intake is thought to have a 'J-shaped' relation to stroke, such that small amounts may be neutral or even protective with regard to stroke incidence, but heavy alcohol intake carries increased risk of stroke….I therefore disagree with Dr. Ziman that it is appropriate to rule out alcohol abuse as a risk factor for Mr. Frost's stroke."); *see also* Aug. 3, 2016 Hr'g Tr. at 42:11-13 ("THE COURT: Okay? Is that something that comes in at the trial? MR. BERNICK: Absolutely. Again, absolutely.").

(c) AbbVie's Additional Points of Interest

With respect to cross-cutting causation issues, Mr. Frost allegedly was a long-term user of AndroGel (1+ years before injury), who was under the age of 65 and had a history of CV risk factors at the time of his heart attack. With respect to cross-cutting failure to warn issues, Mr. Frost's AndroGel prescription and injury occurred after the Basaria RCT was published on June 30, 2010, but before further studies reported an association with CV risk in 2013-14.

3. Jeffrey Konrad (Case No. 15-cv-00966)

(a) Background

(i) Alleged injury: Heart attack

(ii) Date of alleged injury: July 9, 2010

(iii) Approximate dates of alleged AndroGel use: May 2010 – June 2010

(iv) Date of birth: January 7, 1961 (current age: 56; age at injury: 49; age at first prescription: 49)

(v) State of residence: Tennessee

(b) Plaintiffs' Additional Points of Interest

The *Konrad* case was selected by both the PSC and AbbVie as a bellwether trial case. Of the seven bellwether trial cases, it was the only trial case proposed by both the PSC and AbbVie. Mr. Konrad's case is thus the logical first trial case. This case covers the core issues in dispute, and will therefore be informative for the parties and the Court. *See* AbbVie's July 25, 2016 Proposal at 14 & Ex. A (noting this case as a "Green" case) (Dkt. Nos. 1406 & 1406-1). For example, Mr. Konrad's cardiovascular injury (heart attack) tests the predominant injury claimed in this MDL with respect to causation and liability. His age at injury (49 years old) is representative of the broader pool, as approximately one-third of the random 100 plaintiffs in the early bellwether discovery pool were between the ages of 45 and 55 years at the time of injury. His case also informs the parties and the Court on the issue of causation in the setting of short-term AndroGel usage, as Mr. Konrad used AndroGel for approximately two months prior to injury. Additionally, the influence of potentially confounding risk factors in this case (*e.g.*, overweight status, hypertension) can also be assessed in the *Konrad* trial. Finally, Mr. Konrad's underlying reason for AndroGel use is consistent with those of a major portion of the plaintiffs in the MDL. "Age-related declines"

in testosterone blood levels were a focus of AbbVie's marketing and promotional strategies. In fact, Mr. Konrad requested AndroGel after having seen specific AndroGel commercials. This fact tests, among other things, the warnings, warranty, marketing claims, and design defect issues.

(c) AbbVie's Additional Points of Interest

The Court already has selected Mr. Konrad's case as the first bellwether trial. Mr. Konrad allegedly was a short-term user of AndroGel (< 90 days pre-injury), who was under the age of 65 and had a history of certain CV risk factors at the time of his heart attack. Plaintiff's experts assert that Mr. Konrad fits into a subpopulation for which the Finkle (2014) observational study reported a statistically significant association between TRT use and CV risk.[4] With respect to cross-cutting failure to warn issues, Mr. Konrad was prescribed AndroGel beginning before the Basaria RCT was published on June 30, 2010, and he experienced a heart attack on July 9, 2010, at about the time of the Basaria publication (but before the Finkle publication in January 2014).

[4] As reflected in AbbVie's pending motions on causation, this contention is based upon an undisputedly false premise.

4. Jesse Mitchell (Case No. 14-cv-09178)

(a) Background

(i) Alleged injury: Heart attack

(ii) Date of alleged injury: November 18, 2012

(iii) Approximate dates of alleged AndroGel use: December 2007 – November 2012

(iv) Date of birth: May 29, 1963 (current age: 53; age at injury: 49; age at first prescription: 44)

(v) State of residence: Oregon

(b) Plaintiffs' Additional Points of Interest

Mr. Mitchell suffered a heart attack, which is the predominant injury claimed in the MDL. Mr. Mitchell's age at injury (49 years old) reflects one-third of the plaintiffs in the randomly selected 100 AbbVie cases, from which the pool of 32 bellwether discovery cases was drawn. The date of Mr. Mitchell's injury (November 2012) further tests the issue of cardiovascular labeling, notice, and marketing issues during the year when most of the random 100 Plaintiffs were injured (35 of the randomly selected plaintiffs had their events in 2012). Mr. Mitchell was also a long-term user of AndroGel, which will inform on the issue of causation for differences in long-term versus short-term usage (approximately one-third of the random 100 cases used the drug for longer than two years). Similarly, Mr. Mitchell had a relatively common cardiovascular risk factor profile at the time of event (hypertension, overweight status), and was also a smoker. Indicative of the case's representativeness, the *Mitchell* case was selected by both the PSC and AbbVie for inclusion among the 32 bellwether discovery cases. *See* AbbVie's Nov. 2, 2015 Proposal at 6 (Dkt. No. 1038); PSC's Nov. 2, 2015 Proposal at 5 (Dkt. No. 1039). AbbVie has further agreed that the case is not an "outlier." *See* AbbVie's July 25, 2016 Proposal at 12, 22 & Ex. A (noting this case as a "Yellow" case)

(Dkt. Nos. 1406 & 1406-1). As set forth below, the PSC proposes that the *Mitchell* case, with its long-term use, later date window, and predominant CV injury (MI), be the second CV case to be tried.

(c) AbbVie's Additional Points of Interest

With respect to cross-cutting causation issues, Mr. Mitchell allegedly was a long-term user of AndroGel (4+ years pre-injury), who was under the age of 65 and had a history of CV risk factors at the time of his heart attack. With respect to cross-cutting failure to warn issues, Mr. Mitchell was prescribed AndroGel beginning before the Basaria RCT was published on June 30, 2010. His use of AndroGel and his heart attack extended after that date, but they occurred before further studies reported an association with CV risk in 2013-14.

As previously discussed in AbbVie's Proposal for Selection of Bellwether Cases for Trial (Doc. No. 1406 at 22), the severe nature of Mr. Mitchell's heart attack and potential subsequent psychological issues make his case unique among the other 3 CV cases remaining after Konrad. Mr. Mitchell was also relatively young (49 years old) at the time of his heart attack. Only about 20 percent of the CV cases in the randomly-selected pool of 100 plaintiffs were under 50 at the time of their CV injuries, and Mr. Konrad (whose case is the first scheduled, bellwether trial) also was 49 at the time of his heart attack.

B. VTE Cases

1. Arthur Myers (Case No. 15-cv-01085)

(a) Background

(i) Alleged injury: Pulmonary embolism

(ii) Date of alleged injury: February 7, 2008

(iii) Approximate dates of alleged AndroGel use: June 2003 – August 2008

(iv) Date of birth: November 12, 1965 (current age: 51; age at injury: 42; age at first prescription: 37)

(v) State of residence: Arizona

(b) Plaintiffs' Additional Points of Interest

The *Myers* case involves causation and liability for the development of a pulmonary embolism. This case presents an opportunity to test VTE causation in the context of long-term AndroGel usage, as Mr. Myers used AndroGel for over five years. Approximately one-third of the Plaintiffs in the pool of 100 randomly selected cases used the product for longer than two years. Mr. Myers used AndroGel seeking increased libido and sexual performance, a common prescription purpose and focus of AbbVie's marketing and promotion. While Mr. Myers age at first prescription (38 years old) and age at injury (42 years old) are on the young side based on the ages for the random 100 cases—only four other plaintiffs were as young when injured—AbbVie concedes that the *Myers* case is *not* an "outlier." *See* AbbVie's July 25, 2016 Proposal at 12, 23 & Ex. A (noting this case as a "Yellow" case) (Dkt. Nos. 1406 & 1406-1). On liability issues, however, Mr. Myers suffered his event in early 2008, a fact that will constrain the liability window at trial, and thus its broader generalizability on notice, warnings, and marketing matters. Indeed, only 5 of the plaintiffs in the random 100 cases suffered their injuries earlier in time than Mr. Myers. As a result, to broaden the information learned in the early bellwether trial cases, the PSC thinks that the bellwether process is best served if the *Myers* case follows the *Nolte* (2012 injury) and *Rowley* (2013 injury) VTE cases in trial sequence. Compared to *Myers*, *Nolte* and *Rowley* implicate far broader liability windows, and a corresponding number of similarly situated plaintiffs (58 of the random 100 plaintiffs were injured in 2012 or earlier, while 88 of the random 100 plaintiffs were injured in 2013 or earlier).

(c) AbbVie's Additional Points of Interest

With respect to cross-cutting causation issues, Mr. Myers allegedly was a long-term user of AndroGel (4+ years pre-injury), who was under the age of 65 and had a history of VTE risk factors (but a hematocrit level within normal lab limits) at the time of his pulmonary embolism. With respect to cross-cutting failure to warn issues, Mr. Myers's first AndroGel prescription and his injury occurred before September 2009, when the FDA first approved an AndroGel patient Medication Guide, which included "clots in the legs" as an adverse reaction, consistent with then approved product labeling for physicians.

2. Robert Nolte (Case No. 14-cv-08135)

(a) Background

(i) Alleged injury: Pulmonary embolism

(ii) Date of alleged injury: November 1, 2012

(iii) Approximate dates of alleged AndroGel use: August 2012 – December 2012

(iv) Date of birth: January 29, 1940 (current age: 77; age at injury: 72; age at first prescription: 72)

(v) State of residence: Arizona

(b) Plaintiffs' Additional Points of Interest

With an alleged injury of pulmonary embolism, the *Nolte* case tests causation and liability for the injury claimed in 44% of the clot cases in the pool of 100 random cases. This case implicates relatively short-term usage (approximately three months) that assists in testing short- versus long-term usage on VTE injury risk. It is noteworthy that approximately 47% of the original 32 bellwether cases used AndroGel for less than a year. Mr. Nolte's November 2012 injury date tests VTE liability during the year during which most Plaintiffs were injured (35 of the 100 randomly selected Plaintiffs had their events in 2012). As the Court is aware, this case was included in the 32 bellwether discovery cases by the Court (*see* Nov. 20, 2015 Minute Entry (Dkt. No. 1068)) to address AbbVie's concerns about age. Mr. Nolte's age at injury (72 years old) is in line with approximately 20% of the pool of 100 random cases, who were 65 years of age or older at the time of injury.

(c) AbbVie's Additional Points of Interest

With respect to cross-cutting causation issues, Mr. Nolte allegedly was a short-term user of AndroGel, who was over age 65 and had a history of VTE risk factors (and one hematocrit reading above normal lab limits) at the time of his pulmonary embolism. With respect to cross-

cutting failure to warn issues, Mr. Nolte's AndroGel prescription and injury occurred after the September 2009 AndroGel Medication Guide discussed above but before the FDA identified "new safety information" regarding VTE in March 2014.

As previously discussed in AbbVie's Proposal for Selection of Bellwether Cases for Trial (Doc. No. 1406 at 20), Mr. Nolte had both an uncommon genetic predisposition for the development of blood clots (Leiden Factor V) and a prior history of clotting. Mr. Nolte also was 72 years old at the time of his first AndroGel prescription. Less than 12 percent of the VTE cases in the randomly selected pool of 100 plaintiffs were over 65 at the time of their first AndroGel prescription, and Mr. Nolte is the only plaintiff who was over 70 at the time of his first prescription.

3. Robert Rowley (Case No. 15-cv-02760)

(a) Background

(i) Alleged injury: Deep vein thrombosis

(ii) Date of alleged injury: April 27, 2013

(iii) Approximate dates of alleged AndroGel use: April 2012 – April 2013

(iv) Date of birth: August 16, 1945 (current age: 71; age at injury: 67; age at first prescription: 66)

(v) State of residence: Utah

(b) Plaintiffs' Additional Points of Interest

The *Rowley* case involves a deep vein thrombosis and an injury date that, on that basis, provides the potential to provide broad information on certain liability issues. The case, however, is complicated by certain atypical diagnoses that present the potential to weaken the applicability of any jury findings to other cases on other liability points and on case-specific causation. For example, Mr. Rowley's past medical history includes references to atypical conditions, including benign testicular tumor (his left testicle was removed in November 1991), which will touch on several issues, including unique risk-benefit arguments concerning AndroGel use particular to Mr. Rowley. Also, he was diagnosed with inflammatory bowel disease (Crohn's disease) and underwent a bowel resection in 1986. AbbVie's experts characterize this condition as a risk factor for venous thromboembolism. *See, e.g.*, General Opinion Report of Sucha Nand, M.D. at 12 (Dec. 6, 2016), claiming that "[c]ertain major medical illnesses, including inflammatory bowel disease (*e.g.*, Crohn's disease, ulcerative colitis)" are "major risk factors" for VTE. Dr. Nand further claims in his case-specific expert report that Mr. Rowley's "severe" Crohn's disease contributed to his DVT. Crohn's disease is a rare, but serious, disease that affects only 0.5% of the population. Litigating the role of this

alleged risk factor will have little, if any, impact on most of the thousands of plaintiffs. Given the focus on this unique alternative cause argument, the PSC believes that, as among the three VTE cases in the trial pool, the parties and Court would be well-served to sequence the *Nolte* case as the first VTE trial case, then proceed with the *Rowley* case.

(c) AbbVie's Additional Points of Interest

With respect to cross-cutting causation issues, Mr. Rowley allegedly was a long-term user of AndroGel, who was over age 65 and had a history of VTE risk factors (but a hematocrit level below normal lab limits) at of the time of his deep vein thrombosis. With respect to cross-cutting issues on failure to warn claims, Mr. Rowley's AndroGel prescription and injury occurred after the September 2009 Medication Guide but before the FDA identified "new safety information" regarding VTE in March 2014.

II. Proposals for AbbVie-Only Bellwether Trial Sequence

A. Plaintiffs' Proposal

The Plaintiffs propose prioritizing the seven AbbVie-only bellwether trial cases in the following sequence:

(1) *Konrad*

(2) *Mitchell*

(3) *Nolte*

(4) *Rowley*

(5) *Myers*

(6) *Cribbs*

(7) *Frost*

Plaintiffs propose trying the *Konrad* case first, as both the PSC and AbbVie selected it as a trial case. As discussed above, this case involves the determination of several cross-cutting and generally applicable issues that will help inform the Court and parties regarding the strengths and weaknesses of the claims and defenses in the litigation as a whole. The PSC proposes *Mitchell* as the second case because, like *Konrad*, it involves a cardiovascular injury with fairly typical and broadly applicable facts. The *Mitchell* case involves a heart attack, which is the predominant injury claimed in the MDL, but with long-term usage and an injury date that tests notice in a later year (2012), which also happens to be the year in which most of the random 100 plaintiffs were injured. Accordingly, trying two bellwether cases involving cardiovascular injuries back-to-back will shed light on issues involving causation, including the role of background cardiovascular risk factors, differences in length of use relative to cardiovascular injury, as well as liability issues driven by the date of injury relative to notice and warnings activity.

Following the two cardiovascular injury cases, the PSC proposes *Nolte* and *Rowley* as the

third and fourth trials because they are representative VTE cases (both were selected by the Court for the pool of 32 discovery cases). As noted above, both *Nolte* and *Rowley* test causation and liability for venous thromboembolism, which is the injury claimed in 44% of the clot cases in the pool of 100 random cases. *Nolte* involves relatively short-term usage (approximately three months) and Rowley tests a longer usage period (approximately one year). Therefore, these cases will compare claims and defenses in both short versus long-term usage with respect to VTE injury risk. Both cases also test the warnings provided with respect to VTE risk and risk-mechanisms prior to the 2014 labeling change required by the FDA on this subject. Mr. Nolte's November 2012 injury date tests VTE liability during the year in which most Plaintiffs were injured (35 of the 100 randomly selected Plaintiffs had their events in 2012). Though the *Rowley* case includes certain unique medical issues (*e.g.*, testicular removal and inflammatory bowel disease), it is more representative than the remaining three cases, *Myers*, *Cribbs*, and *Frost*.

The PSC proposes setting *Myers* as the fifth case in sequence. Like *Nolte* and *Rowley*, this case involves venous thromboembolism. With AndroGel usage for over five years, this case presents an opportunity to test causation in the context of long-term usage with respect to VTE. Approximately one-third of the plaintiffs in the pool of 100 randomly selected cases used the drug for longer than two years. However, the limited liability window at issue in *Myers*, and consequent limited generalizability to a broad collection of other cases, argues for the case proceeding only after the other VTE cases (*Nolte* and *Rowley*) are tried.

The last two cases in sequence should be the *Cribbs* and *Frost* cases. These cases involve unique legal and/or factual issues that are likely to render the information gleaned from trial of these cases less broadly generalizable to other cases in the MDL. With *Cribbs*, the presumed applicability of North Carolina substantive law is likely to shape the trial proofs of

that case in a manner that will not be generally applicable to the majority of other cases in the MDL on warnings adequacy (and, relatedly, proximate cause). Similarly, the significant dispute over AndroGel usage in the *Frost* case, *see supra*, and significant social issues (including alcoholism that will be presented as a risk factor) will likely overwhelm, thus minimizing lessons to be applied to other cases on both general and specific causation.

Finally, if the Court would prefer an alternative to it sequencing the cases for each of the trial settings, the Court could proceed with a modified version of alternating party trial selections—a technique often employed in MDLs—to wit: given the joint proposal by the PSC and AbbVie of *Konrad* as a trial case, it should be set as the first case in sequence; thereafter, the parties, beginning with the PSC then followed by AbbVie, will alternate the selection of trial cases from the remaining eligible trial cases to populate the next four trial case slots (sequence numbers two through five); finally, the Court could select the sixth case in sequence from the remaining two eligible trial cases, on such grounds that the Court determines are appropriate. To enable appropriate pre-trial, witness, and counsel preparations under this alternative proposal, the PSC proposes that the selection by the parties of the PSC's and AbbVie's trial plaintiffs for trials two through five[5] be completed by March 10, 2017.

B. AbbVie's Proposal

The Court's prior rulings do not adopt a specific plan for determining the order of the bellwether trials. But they do provide some guidance. *First*, the Court has always contemplated that the bellwether trials would be evenly split between CV and VTE cases. *See, e.g.*, CMO No. 14, Doc. No. 1588 at 2-3 (directing Plaintiffs and Defendants to identify eight VTE cases and

[5] For purposes of this alternative, the first trial case in sequence is assumed to be *Konrad* and the sixth in sequence is the plaintiff selected by the Court following the parties' selection of the plaintiffs for positions two through five.

eight CV cases to serve as bellwether discovery plaintiffs). More recently, the Court has scheduled four bellwether trials. It therefore makes sense to split the four settings evenly between CV and VTE cases. *Second*, dispositive motions are pending in all of the remaining bellwether cases, and CMO No. 14 contemplates that the Court will endeavor to rule on these motions by May 8, 2017. Because there appears to be agreement that the trial order should be set in advance of those rulings, it also makes sense to order all of the bellwether cases so that a replacement case can be determined immediately in the event a case is dismissed for any reason. *Third*, the parties and the Court have agreed that Konrad will be tried first, beginning on June 5, 2017. AbbVie suggests that the July 3, 2017 setting be a second CV case, followed by two VTE cases. This approach will ensure that the four currently scheduled trials are split evenly between CV and VTE cases while limiting the number of times that the parties will have to switch back and forth between CV and VTE trials, given the relatively short period between trials (approximately one week as per CMO 14).

If the Court decides to adopt this approach, it remains to settle upon a method for ordering the 3 remaining CV cases after Konrad, and separately, the three VTE cases. Three methods for making decisions about bellwethers have been considered in the past: selection by the parties, random selection, and selection by the Court based upon representativeness. Of the three approaches, AbbVie believes that random selection is the most appropriate method for deciding upon the order of trials.

Allowing the parties to choose the trial order, for example, by alternating picks, will mean that the party that gets the first pick for each type of case (CV or VTE) will also get the last pick, thereby determining two of the three cases for each disease type. Trying to right this imbalance by allowing one party to pick the first CV case and the other to pick the first VTE

case just means that the same problem will affect both types of cases. While it is always possible to imagine other protocols for the parties to make their choices, it will be difficult to eliminate the "gaming" element entirely. Nor will any apparent value be achieved in leaving the matter to counsel's choice.

The alternative approach of having the Court determine the order based upon representativeness has the virtue of avoiding gaming and adopting a neutral test. If the Court uses this approach, AbbVie proposes the following order based upon the facts set forth above for each of the cases.

CV cases: Konrad, Cribbs, Frost, Mitchell. Konrad's experts opine that his case fits a subpopulation for which an epidemiological study (Finkle (2014)) has reported a statistically significant association between TRT use and CV risk. The Konrad case also covers the labelling period prior to publication of the Basaria RCT at the end of June 2010. Turning, then, to the remaining CV cases – Cribbs, Frost, and Mitchell – they are all similar to one another in that none fit any of the subpopulations for which an epidemiological study has reported a statistically significant CV association. So they all will present the issue of whether TRT poses a risk to TRT users overall. Likewise, with respect to failure to warn issues, all three involve prescriptions and injuries in the labelling period between the publication of the Basaria RCT in June 2010 and the publication of the later CV studies from April 2013 to January 2014. However, as noted above, the Mitchell case has distinctive features that differentiate it from the other CV cases and make it less representative of the bellwether pool. Those features are the unusual severity of his heart attack, his subsequent psychological issues, and his relatively young age. As to Frost, AbbVie recognizes (and Plaintiffs have highlighted previously) that his case presents a number of personal issues. *See, e.g.*, Doc No. 1407 (PSC's Proposal for Initial

AbbVie-Only Bellwether Trial Picks) at 30-31. Whether these issues are featured at trial, however, is a question for a later date. *See* Aug. 3, 2016 Hr'g Tr. at 42:6-45:14. Also, since the Frost case is the only stroke case among the seven bellwethers, moving it up in the trial order would serve to represent that group of injuries.

VTE cases: Myers, Rowley, Nolte. As to the 3 bellwether VTE cases, the cases are all similar in that none of the cases fit the subpopulations for which the Martinez (2016) study reported a significant association between TRT use and VTE. With respect to failure to warn issues, the Myers case involves labelling prior to the September 2009 Medication Guide, and the Rowley and Nolte cases involve the later period running from after publication of the Medication Guide to the 2014 FDA investigation. It would therefore make sense to put Myers either first or second in the trial order and one of the two remaining cases at the end of the order. AbbVie suggests that Nolte be put at the end. As discussed above, Nolte had an uncommon genetic predisposition (less than 6% prevalence),[6] a prior history of clotting, and was 72 at the time of his prescription and injury. Mr. Nolte did have a hematocrit reading slightly above normal lab limits as of the time of his pulmonary embolism, thereby framing another cross-cutting issue. But the Court should also be aware that this reading was well within *his* normal range since he had hematocrit readings above 50 percent both before his first AndroGel prescription and after he stopped using AndroGel.

Returning then to random selection, AbbVie believes that this approach is the simplest and the most neutral. It is the simplest because the parties can implement it without taking up more of the Court's time. The parties need only go online and use an available randomizing

[6] *See* Previtali E, Bucciarelli P, Passamonti SM, Martinelli I. *Risk factors for venous and arterial thrombosis*. Blood Transfus. 2011;9:120–138 at 124, Table IV; *see also* Aug. 3, 2016 Hr'g Tr. at 60:25-64:6.

program, as they did earlier in the case. It is the most neutral path because the order of trials is determined by chance alone, using a computerized coin toss. And it is the most appropriate method because the Court has already expressed the view that the trial order does not implicate any substantive judicial interest. Thus, as discussed above, AbbVie proposes that the Court randomly select the order of cases to be tried after Mr. Konrad's, and respectfully requests that the Court first try two CV bellwether cases, followed by two VTE bellwether cases, followed by the third CV case, the third VTE case, and then the fourth and final CV case.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 27, 2017, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

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