UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545
This Document Relates to All Cases	Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
	Tronorable Manual W 1 President

JOINT STATUS REPORT REGARDING REPLENISHMENT OF ABBVIE-ONLY BELLWETHER TRIAL POOL

The Court directed counsel to file this joint report regarding the parties' discussions and respective positions regarding the Court's proposal to add more cases to the AbbVie bellwether trial list.

PSC's Proposal:

In accordance with the Court's Docket Entry dated May 18, 2017, (ECF. No. 1937), the PSC respectfully submits the following as a proposal to increase the number of cardiovascular ("CV") cases in the AbbVie trial pool, and to add one additional Venous Thromboembolism ("VTE") case as directed by the Court in said Docket Entry and per the instructions from the Court at the hearing on May 18, 2017.¹

In light of AbbVie's filed a pleading consenting to the *Konrad* case staying in its current trial slot (ECF No. 1947) as well as CMO 55 striking the purported statute of limitations and statute of repose affirmative defenses, it appears that the *Konrad* case is being tried June 5, 2017. Nevertheless, because the Court requested that a bellwether replacement process be proposed,

¹ The PSC reached out to AbbVie's counsel on Friday, May 19, 2017, in an effort to meet and confer concerning the selection process but in light of numerous differences, we do not foresee an agreed-up plan being viable.

which includes three new (CV) cases and one new VTE case, the PSC submits the following alternative proposals. (Transcript of Proceedings at 24:12-18, May 18, 2017).

Even with the *Konrad* case being tried on June 5th, per the Court's directive, the PSC respectfully proposes the following to re-populate certain of the cases that were removed from the trial pool. First, the PSC proposes that the David Deel case be selected as a replacement CV case, and the Lance Blanck case be selected as a replacement VTE case. Both cases can be easily added into the bellwether trial schedule with discovery to be completed in accordance with the schedule set forth below. Furthermore, each of these cases is from the existing pool of 24 cases that have already undergone "Core Discovery," as part of the original AbbVie bellwether process. Using these two cases as replacement cases will bring the AbbVie bellwether trial pool from 6 cases back to the original 8 cases.

Second, should the Court determine that adding additional/replacement CV cases is warranted to reach the Court's goals, the PSC respectfully submits that the PSC's proposal set forth in Section II herein should be adopted, because it will yield representative cases and because AbbVie should have little, if any, say in further selection of representative cases.

I. Proposal for Replacing One New CV Case and One New VTE Case from the Existing Bellwether Pool of AbbVie Cases²

The PSC respectfully submits that the process for selecting the new cases should be broken into phases, should the Court ultimately conclude a new AbbVie CV case pool is required. First, substituting one CV case and one VTE case into the exiting bellwether trial schedule, and second

² As the Court will recall, there was first a pool of 100 AbbVie only cases that were selected randomly. From this pool, the sides each selected, what they believed were 16 representative cases (8 CV cases per side and 8 VTE cases per side) for a total of 32 bellwether cases that would undergo Core Discovery, as defined by CMO 14. From these 32 cases, the parties were ultimately left with 24 cases from which the Court selected 8 final trial cases based upon advocacy and arguments from AbbVie and the PSC.

determining a process to replenish a new CV pool, if needed. For addressing the immediate task at hand – to replace one CV case and one VTE case – the PSC proposes the one CV case be *David Deel and Diana Deel v. AbbVie, Inc. and Abbott Laboratories, Inc.*, No. 14-cv-10435, (N.D. Ill. 2014), and the one VTE case be *Lance Blanck and Kimberly Blanck v. AbbVie, Inc. and Abbott Laboratories, Inc.*, No. 15-cv-01077, (N.D. Ill. 2015

As noted above, both cases were in the final pool of 24 bellwether cases. Thus, both cases have been through "Core Discovery." Furthermore, the *Deel* case was already a "back-up" trial case pursuant to CMO 30.³

While the PSC believes that AbbVie intends to advocate that all new cases should be taken from the existing pool(s), the PSC submits that the urgency of this issue requires the immediate selection of two new cases – one CV and one VTE – to make the trial pool essentially whole. And for these two cases, the PSC submits that they can be selected from the existing bellwether pool, and further, submits those two replacement cases should be *Deel* (CV case) and *Blanck* (VTE case).

However, aside from the *Deel* and *Blanck* cases, there is no need to try and to select additional cases from the existing pools. First, the PSC believes it will be impossible to find that number of truly representative cases from what remains in the existing pools. Moreover, there are inherent problems and concerns in selecting cases from the existing pools. The PSC believes that

³ Per CMO 30, the *Cribbs* case was conditionally selected pending AbbVie's counsel ability to locate and produce the sales representative for deposition within approximately a two-week window as Ordered by the Court. As the Plaintiffs realized, when faced with the prospect of the *Cribbs* case being in the final pool, Defendants were suddenly able to locate and produce the missing sales representative in the last weeks of August. The Court similarly noted, "That's why I wrote the order the way I did. You want this case, you are going to find him ... I am not surprised." (Transcript of Proceedings at 32:22-33:2, August 11, 2016, ECF. No. 1442). Notwithstanding, the *David Deel* case was the back-up case to replace *Cribbs*. In fact, as it ultimately turned out, *Cribbs* was dismissed on summary judgment; indeed perhaps underscoring its lack of representativeness for a trial.

selecting cases either from the remaining pool of 24 cases or from the remaining pool of 100 cases would be the least effective means of selecting new representative cases for additional future bellwether trials on "cross cutting issues." The reason is because, by definition, the cases that remain in the pool are those that were neither proposed by the parties, nor selected by the Court from those that were proposed. If the purpose of choosing new cases for bellwether trials is to enlarge the pool of cases available that are truly representative, then selecting from those that have already missed the cut would not appear to satisfy this objective. Second, and as noted in detail in Section II, below, there is less of an urgency to work-up and have trial ready additional CV bellwether trial cases. Notwithstanding this, as set forth in Section II, the PSC's proposal for any additional CV cases (beyond *Deel*) can be selected, have "Core Discovery" done, picked for trial, and be trial ready by mid/late October 2017.

The obvious advantage of using cases already in the pool is the fact that some work has been done in these cases that will result in the parties needing less time to get these cases to a position where they will be ready for trial. That said, the PSC's compromised approach would be to select the *Deel* case (CV replacement) and the *Blanck* case (VTE replacement) from the original pool. The remaining CV cases, if the Court still wants any, can be chosen from a new pool as set forth in Section II, below.

This is proposed by the PSC because there are two cases in the existing pool that do not suffer from the same lack of representativeness issues as those not chosen in the first instance. Those two cases are *Deel* and *Blanck* (VTE).

As noted in the proposed schedule below, selecting these cases, albeit, adding tremendous more work to the PSC and AbbVie (which the PSC is willing to endeavor) will still have the Court

on target for a CV trial case in September, 2017 (and will also have another VTE case fully worked up by that time too).

The *Deel* case should be the next CV case that is tried following the trials of *Konrad* and *Mitchell*. The *Deel* case was fully worked up in the "Core Discovery" bellwether process, and as noted in footnote 3, above, was actually "on deck" to be included should the *Cribbs* case not be permitted to remain in the final trial pool. As such, the PSC would propose that the *Deel* case could proceed with the following schedule, and be ready by mid/late September, 2017, which would be still keeping with the Court's schedule.

- Completion of any final fact discovery by June 23, 2017
- Plaintiffs shall make case-specific expert disclosures pursuant to Fed. R. Civ. P. 26(a)(2) by June 30, 2017
- Defendants shall make case-specific expert disclosures pursuant to Fed. R. Civ. P. 26(a)(2) by July 7, 2017
- Plaintiffs shall make any case-specific rebuttal disclosures allowed by the court by July 14, 2017
- Depositions of all experts (that are not duplicative of depositions already taken in the AbbVie bellwether process and depositions shall not be entitled on topics previously set forth in expert reports) shall be completed by July 28, 2017
- Any non-duplicative motions for summary judgment or for partial summary judgment shall be filed by August 4, 2017
- Any non-duplicative motions seeking to challenge expert testimony pursuant to *Daubert* shall be filed by August 4, 2017
- Responses to summary judgment and *Daubert* motions shall be filed by August 25, 2017
- The parties will submit a proposed Pretrial Order and Pretrial schedule to the Court by September 8 2017
- Trial of the *Deel* case to begin on September 18, 2017.

Any objection by AbbVie to including the *Deel* case should be rejected by the Court. The *Deel* case is the next logical case to slide into the mix, because it has always been contemplated as the "back-up" CV case, the Court's Minute Order makes evident the need to add at least one back-up CV case. Moreover, Mr. Deel is represented by a PSC firm (Morgan & Morgan) and indeed, having new lawyers, but still PSC lawyers, involved with trial also serves a representative purpose.

For the Court's recollection, the facts of the *Deel* case are as follows: Mr. Deel is a resident of Kentucky and was 54 years old when he suffered a heart attack on January 16, 2014, while on vacation in Mexico. He used AndroGel from September 5, 2008 until the time of his heart attack, and began using AndroGel to treat erectile dysfunction and fatigue he believed to be caused by low testosterone. As a result of his heart attack, Mr. Deel is disabled and had to retire from work.

As laid out in greater detail in the PSC's bellwether submission dated July 25, 2016, Mr. Deel's case is representative for the purposes of the bellwether process because many of the facts of his case are typical of the overall pool of cases. (ECF. No. 1407 at p. 17-18). Mr. Deel's age range during his TRT use was consistent with AbbVie's target market for AndroGel. While Mr. Deel did have some risk factors for heart attack, those risk factors are fairly typical of a man of his age and were not excessive. The issues that Mr. Deel was treating with AndroGel are also characteristic of plaintiffs in this litigation. For these reasons, the *Deel* case is the most logical case to add to the AbbVie bellwether trial sequence.

While AbbVie at one time sought to claim this was a mixed use case, we believe they ultimately rejected this argument or should have. 4

⁴ The PSC addressed this in their initial briefing on the AbbVie bellwether trial picks in July of 2016, but it bears repeating that Mr. Deel's case, despite a single reference to Androderm, is not a mixed use case because Mr. Deel never filled a prescription for Androderm, and repeatedly denied using any testosterone product other than AndroGel in his deposition.

The VTE case that should be selected from the existing pool is Lance Blanck.⁵ Mr. Blanck is a resident of California. He began taking AndroGel to address a lack of energy and reduced libido. He suffered a deep vein thrombosis ("DVT") and a pulmonary embolism ("PE") on December 24, 2013. These thromboembolic events caused him to forego a knee surgery that he was previously scheduled to have.

As explained in the PSC's bellwether submission dated July 25, 2016, and similar to the Deel case, Mr. Blanck's case is representative for the purposes of the bellwether process because it shares many commonalities with the overall pool of cases and will therefore be instructive to the parties and the Court if tried. (ECF. No. 1407 at p. 22). Specifically, Mr. Blanck was 54 years old at the time of his injury, and 12 of the 24 cases in the eligible pool involved plaintiffs within the ages of 51 and 60. Additionally, Mr. Blanck was prescribed AndroGel to treat symptoms including fatigue and sexual dysfunction, which is typical of many other plaintiffs in this litigation. Mr. Blanck's risk factors are all shared with many other plaintiffs in the overall pool of cases, especially his hypertension which is present in approximately 15 of the 24 eligible cases. Additionally, Mr. Blanck's case does not involve any unique alternative causation factors which distinguish it from other cases. Because "Core Discovery" has been completed, the *Blanck* case could be worked up on the same schedule proposed above for the *Deel* case.

Finally, any objection by AbbVie to either the *Deel* case or *Blanck* case proceeding should be rejected for multiple reasons. First, both cases have had "Core-Discovery" conducted and are therefore advanced. Second, the *Deel* case was already selected as a quasi "back-up". Third, AbbVie should be given little, if any, role or leeway in selecting representative cases given their

⁵ Mr. Blanck is represented by Ross Feller & Casey and attorney Mark Hoffman, Esq., who is a member of the PSC. So like *Deel*, this case will involve another PSC firm.

actions to date in the process and given the history of what has transpired with *Konrad*, *Garcia*, and *Cribbs*.

II. Proposal for Selection of Entirely New AbbVie Bellwether Cases

Should the Court determine adding only two cases to the trial pool (the *Deel* and the *Blanck* cases) will not be sufficient, the PSC proposes that it be tasked with selecting any additional cases for bellwether process and trials – and these cases *not* come from either of the existing pool(s).

As the Court is aware, the existing system is designed so that if a bellwether case set for trial drops out for any reason, then the next case on the schedule moves up to take its place so that no trial date is lost. This system puts tremendous pressure on the PSC because if this contingency occurs, especially if close to trial, it is extremely burdensome on the PSC to suddenly advance all dates that the out-of-town Plaintiffs and experts are required to come to trial. This pressure is designed to be a disincentive to the PSC to dismiss bellwether cases before trial to gain advantage or otherwise game the system, but what was not foreseen until *Konrad* was that the Defendant could engineer a claim or defense at the last minute to assert a dispositive unique case-specific issue (which would have otherwise made the case non-representative), and thus force the PSC to scramble to prepare for a new case to be tried in the same time slot.

Given AbbVie's track record with respect to its efforts to game the bellwether process, the PSC respectfully submits that AbbVie should not be involved in the selection process going forward.⁶

⁶ As the Court will recall from the initial proposals (*see* AbbVie Inc. and Abbott Laboratories' Proposal at pp. 14-16, July 25, 2016, ECF. No. 1406), of the three VTE cases AbbVie proposed to the Court as representative, two of these cases have been shown to be completely unrepresentative. First, in the *Garcia* case, AbbVie advocated for this case to be included in the trial pool despite the fact that it involved a highly unique issue. Mr. Garcia's injury was shown by deposition testimony to predate the plaintiff's use of AndroGel. This unique issue was raised in the PSC's bellwether proposal in July of 2016. (PSC's Proposal at p. 32, July 25, 2016, ECF. No. 1407). Despite this, AbbVie continued to advocate for the case's inclusion as a bellwether pick (*see* Transcript of Proceedings 59:15-, August 3, 2016, ECF. No. 1429), and then

Because the burden of this "dismiss and replace" system clearly rests with the PSC, and the only attempt at a pre-trial dismissal to date has been by the Defendant, the PSC proposes that it should be tasked with choosing the new cases for inclusion in the AbbVie bellwether trial slate. By tasking the PSC with the selection of the replacement cases, it forces the PSC to select cases that will not be dismissed before trial, and prevents the Defendant from selecting cases that it can use to ambush the PSC as it did in the *Konrad* case or selecting other non-representative cases. Moreover, in light of the late-in-the-process posture of the bellwether plan, having cases that the PSC selects and knows can be worked up efficiently and quickly makes additional sense and is in line with the goal of having bellwether trials.

Should the Court desire new cases be added to the pool, the PSC proposes that the PSC select six (6) new AbbVie-only cases that they believe are representative, which will go through "Core Discovery," as that term is defined in CMO 14. Following expedited "Core Discovery", these six (6) cases can be narrowed down to two (2) final cases that can be trial cases, one CV case and one VTE case. The PSC proposes winnowing down the six (6) cases so as to ensure the most representative cases are ultimately selected for trial. The PSC proposes that the Court and PSC select the cases. AbbVie, in light of their documented gamesmanship in the process, 5 should not be permitted to take part in selecting the cases whatsoever.

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sought sanctions when the case was ultimately removed from the trial pool, blaming the PSC for allowing the case to remain in the pool when the PSC had advocated for its removal. (AbbVie's Motion for Sanctions, November 30, 2016, ECF. No. 1620). Second in *Shephard*, which the Court excluded, AbbVie advocated for inclusion of a case involving a plaintiff who not only had a higher than average number of risk factors for DVT, but also had a history of very severe mental illness, both of which made the plaintiff and his case highly unrepresentative of the overall pool of cases. (PSC's Proposal at pp. 36-37, July 25, 2016, ECF. No. 1407). Of course, the Court is familiar with the issues surrounding *Cribbs*, which was advocated for by AbbVie and opposed by the PSC and now *Konrad*, which AbbVie just announced as having a unique case specific issue which AbbVie claims to only just discovered. *See. e.g.* CMO 55. All of which point to any future cases being populated/determined without significant, if any, input from AbbVie.

⁷ The gamesmanship began with the delays repeatedly embedded by AbbVie in the entire discovery and bellwether process. The bellwether schedule laid out in CMO 14 has been amended four times so far, with three of those amendments being prompted by a submission or motion by AbbVie (*See* ECF. Nos. 758,

More specifically, the PSC proposes and will plan to select the six (6) representative cases by June 13, 2017. Thereafter Core Discovery can be conducted in eight (8) weeks, by August 11, 2017. Following Core Discovery, by August 16, 2017, the initial two trial cases can be selected by one of the following methods: the parties jointly agreeing on the two (2) cases, the PSC selecting the two (2) cases, or the Court and PSC selecting the two (2) cases. Following this, expert discovery will proceed as follows:

- Plaintiffs shall make case specific expert disclosures and supplement generic expert disclosures as necessary in the final two cases, pursuant to Fed. R. Civ. P. 26(a)(2) by August 18, 2017
- Defendants shall make expert disclosures and supplement generic expert disclosures as necessary in the final two cases, Fed. R. Civ. P. 26(a)(2)by September 1, 2017
- Plaintiffs shall make any rebuttal disclosures in the final two cases, as allowed by the court by September 11, 2017
- Depositions of all experts (that are not duplicative of depositions already taken in the AbbVie bellwether process) shall be completed by September 22, 2017
- Any motion for summary judgment or for partial summary judgment shall be filed by September 22, 2017
- Any motions seeking to challenge expert testimony pursuant to *Daubert* shall be filed by September 22, 2017
- Responses to summary judgment and *Daubert* motions shall be filed by October 16, 2017
- The parties will submit a proposed Pretrial Order and Pretrial schedule to the Court by October 24, 2017

^{1038,} and 1249). This was followed by AbbVie's selection of the *Garcia* case, despite the PSC's strong warning not to select the case. *See* CMO 51 at p. 1. Thereafter, the sudden ability to locate the sales representative in the *Cribbs* case, and now the situation that AbbVie created by lying in wait on the *Konrad* case. There are other examples of AbbVie's gamesmanship throughout the litigation, but they are not necessarily germane to the problems they caused and sought to cause in the bellwether trial process, the issue at bar now.

In summary, two new additional CV cases can be trial ready by mid-October, 2017, approximately 5 months from now. More importantly, there is no way to possibly try cases any sooner, given the already existing trial schedule. Therefore, while AbbVie will likely strenuously argue for the replacement CV cases to come only from the existing pools, the PSC's compromise is to take one, the *Deel* case which already was a quasi-"back-up," but use a new pool for the additional two CV cases the Court suggested it might need. Moreover, given the existing trial schedule as well as the proposed schedule above, there is no urgent timing that requires selecting the cases from the current pool of either 24, or the remaining 100 based on the argument "work was already done" or "they are more ready". The risk of selecting cases that the parties both passed over in their representativeness analyses is substantial, and thus there is a need to have a more representative, fresher, and cleaner pool. From this new pool, the parties have ample time to conduct Core Discovery, then narrow the pool to two (2) finalists and engage in expert work-ups all by mid-October, 2017. Thus, there is no pressing time concern that warrants dipping into the current pool for the additional two CV cases.

Indeed, based upon CMO 55 it appears *Konrad* will be tried in June 2017, this will then allow for the *Mitchell* case to be tried in July, 2017 (as scheduled), and the *Deel* case to be substituted for the September trial slot, (where *Cribbs* was previously slated), and still have two more AbbVie CV cases ready to be tried after *Deel*.

While the PSC appreciates that AbbVie will likely argue that we should take any new cases from the existing pool of 24 that have already had Core Discovery done, or take any additional cases from the larger random pool of 100, this is flawed for a few reasons. First, for the randomly selected group of 100 cases, the parties have already selected what they believe are the most representative and that comprised the pool of 32. (*See* Transcript of Proceedings, August 18, 2015,

ECF. No. 946. Then from the reduced pool of 32 (where each side selected 16) – 8 CV cases and 8 VTE cases), the parties identified the representativeness (or not) of the remaining 24 in their briefing last year, which led to the Court selecting the final eight cases in CMO 30. *See* AbbVie Inc. and Abbott Laboratories' Proposal, July 25, 2016, ECF. No. 1406 *and* PSC's Proposal, July 25, 2016, ECF. No. 1407. As such, any argument that we should select more cases either from the pool of 100 or from what is left in the pool of 24 should be rejected as those cases clearly contain non-representative cases as already determined by the parties.

Fundamentally, if there is any doubt that the cases that remain are not the ideally representative they should be rejected. The entire point of the bellwether process is to prepare for trial and try cases that are representative, and therefore instructive to all parties as to the ultimate outcome of the litigation. Therefore, choosing additional cases from a new set of cases guarantees the best chance of more representative cases than exist in the already reviewed 24, or those that might be in the remaining 100. Thus, while it may require some more work to get these cases worked up for trial, this work impacts the PSC as much (if not more) than AbbVie and their nearly limitless resources. Furthermore, the earliest a new pool of cases would be available for trial would be October 2017. As such, the timeline and schedule proposed by the PSC for a new group of six case to be narrowed to ultimately two (2) trial ready finalists is very doable.

Simply put, AbbVie's view of "representativeness" is not a fair and accurate review. History has demonstrated that AbbVie's intent all along was to derail any process by any means. Such conduct should not be further encouraged by permitting AbbVie to have a hand in selection of the additional cases. Instead the PSC's proposal for selecting any replacement/additional CV cases after the *Deel* case should, respectfully, be adopted.

III. Conclusion

The PSC proposes to have the *Deel* and *Blanck* cases added into the bellwether trial schedule with discovery to be completed in accordance with the schedule laid out herein in Section I, above. This will provide a near-ready CV case and a near ready VTE case to bring the bellwether trial pool back to eight (8) cases.

Should the Court determine that adding two additional/replacement CV cases is warranted to reach the Court's goals, the PSC respectfully submits that the PSC should be permitted to select six (6) AbbVie only CV cases as detailed above.

AbbVie's Proposal:

Eighteen months ago and after extensive briefing and four hearings, the Court crafted a bellwether selection process tailored to pick cases that were both "representative" of the claimant pool and "productive" in framing cross-cutting issues for pretrial proceedings and trial. That process charted a middle path between AbbVie's proposal of randomized selection and the PSC's proposal of selection by the parties. And it has been implemented with notable success. We have gotten to the eve of trial with 6 of the 8 trial bellwethers in place and ready to go. One case (*Cribbs*) was decided on summary judgment. A second, *Garcia*, was dropped for lack of expert testimony on specific causation.

AbbVie believes the Court should stay the course in selecting two cases (1 CV and 1 VTE), which would bring the total back to eight. We already have 16 more cases to work with, all of which have gone through core discovery of medical records and depositions. It remains only to pick the most representative of them. The Court should permit each side to select two cases (1 CV

and 1 VTE), and the Court should choose the most representative of them to be replacements. If the Court has concern about other trial cases dropping from the trial schedule, it also could choose one or two backup cases from the parties' selections, assuming they are representative.

It appears that the PSC will ask the Court to allow the PSC to select two the replacement cases from the existing pool, and that they will go further to propose that they alone would supplement the existing pool by choosing additional new cases from outside the pool. That of course cannot be justified under any notion of fairness, much less can it produce timely and representative results. AbbVie does not believe there is a need to go beyond the pool of 16 cases at this time, but if the Court wishes to put them to the side and choose new cases, it should draw six at random from the larger pool of 100 cases that was already randomly selected. Allowing one side to choose all replacement and replenishment cases would unfairly and irretrievably skew the bellwether trial pool.

I. The Court's chosen approach to bellwether selection was sound and has worked.

We will be brief here. The Court will well-recall the very different proposals presented by each side in August, 2015. AbbVie proposed a random selection of all 32 discovery bellwethers, taken from the existing pool of approximately 666 cases in which the plaintiffs had completed a PFS by the June 15, 2015 deadline set by the Court. Amended CMO No. 14, at I.A (Doc. No. 793). The randomization program would also be designed to pick a random set of 32 cases that, based upon the PFS, framed cross cutting issues. The PSC proposed party selections. PSC's Memorandum in Support of its Proposal for Selection of AbbVie-Only Bellwether Discovery Cases, at 2 (Doc. No. 933).

The approach chosen by the Court was a hybrid of randomization, party selection, and the Court itself acting as a final "arbitrator." Second Amended CMO No. 14, at I-II (Doc. No. 1089).

One-hundred cases were selected with an agreed randomizer. The PSC then successfully obtained consents from the plaintiffs to have their cases tried before the Court. Each side then proposed 16 discovery bellwether candidates, which the Court identified as the bellwether discovery pool in its Second Amended CMO No. 14. Core discovery then proceeded and took seven months to complete (for 24 of 32 cases). During the process, it emerged that six bellwethers had used other testosterone replacement therapy ("TRT") products in addition to AndroGel. The Court ordered that these cases be dropped as discovery bellwethers. Third Amended CMO No. 14, at I.C (Doc. No. 1287). An additional two cases were dropped by agreement, one because there was evidence of mixed use and one because the parties discovered unique facts about the Plaintiff's alleged product usage, making both non-representative. This left 24 cases for which "core discovery" was completed.

Following the completion of core discovery, the parties proposed eight trial bellwethers and objected to one another's proposals. *See generally* AbbVie Proposal for Selection of Bellwether Cases for Trial (Doc. No. 1406); PSC Proposal for Selection of Bellwether Cases for Trial (Doc. No. 1407). For its own part, AbbVie chose cases that both covered cross-cutting issues and, knowing that plaintiffs would do the same, also presented favorable prospects at trial. AbbVie also limited its objections to those cases which it felt were outliers, comprising three of the eight selected by Plaintiffs. Plaintiffs objected to all of AbbVie's proposals save one. On August 4, 2016, the Court ruled on objections and selected the eight trial bellwethers as representative. CMO No. 30 (Doc. No. 1428). Discovery and trial preparation have proceeded since.

II. AbbVie proposes to choose additional bellwether cases with already completed core discovery.

AbbVie believes that the Court should stay on the same path in filling the two trial bellwether slots that are now empty. This would: (a) preserve the important requirements of

fairness and "representativeness;" (b) preserve the value of the massive discovery conducted in the sixteen remaining cases (30,000 pages of medical records and 55 depositions); and (c) avoid new massive and time-consuming discovery and thereby preserve the existing trial schedule. On the last point, direct experience in this litigation shows that: (1) getting medical records takes at least two to three months; (2) each case entails about seven case-specific fact depositions (plaintiff, spouse, prescriber, multiple treaters, and multiple sales reps, managers), which in the first round was broken into seven months of "core" discovery in all bellwethers, followed by three months of additional discovery for the trial picks; (3) plaintiffs will seek to depose other third parties, such as other defendants and other percipient witnesses who testify to historical liability matters; and (4) the parties will have three months of case specific expert discovery, involving experts in cardiology, and endocrinology/urology.

By contrast, if the Court were to select two additional trial picks from this pool (or three to add a buffer), the parties have a higher probability of completing fact and expert discovery by the end of the year or shortly thereafter. The cases then could proceed to trial in the second quarter, following dispositive motion practice and completion of the pretrial order.

AbbVie is mindful of the Court's concerns expressed last week that "we are getting closer to the bottom of the barrel" of the discovery pool. But the process followed to date should help to put that concern into perspective. First, all of the discovery bellwethers came from a randomly selected pool of 100. That group was neither the bottom of the pool nor the top. From that point on, the conduct of core discovery provided further assurance of representativeness to the extent that more was learned about the cases themselves. At that point, the choice of the parties framed the pool of cases presented to the Court for selection. Any discovery bellwether case not rejected by the Court or by agreement of the parties as an outlier is just as representative of the claimant

pool as the discovery bellwether group was, and is representative.⁸ If the parties' initial bellwether trial proposals are considered, they were in agreement that the following CV cases are outliers: Anthony Long (No. 14-cv-06996);⁹ Roccie Truax (No. 14-cv-02935);¹⁰ and David White (No. 14-cv-03818).¹¹ As to VTE cases, the parties' initial bellwether trial proposals were in agreement that the following cases are outliers: Richard Cannon (No. 15-cv-01484);¹² Robert Cripe (No. 14-cv-00843);¹³ Jesse Patridge (No. 14-cv-7960).¹⁴

This leaves four CV cases and six VTE cases for consideration. From these cases, AbbVie proposes that the Court select 1 CV cases and 1 VTE case¹⁵ as follows.

CV Cases

Here are the four remaining bellwether trial additions presented in AbbVie's order of preference:

Randy Martina (No. 14-cv-08598): Mr. Martina was prescribed AndroGel 1.62% between March 2012 and January 2014. He suffered an MI while on AndroGel, and a stroke six weeks after discontinuing AndroGel. Mr. Martina is an adequate substitution for the dismissed *Cribbs* case, because they both test similar cross-cutting issues. Both Plaintiffs were under 65 with no history of heart disease at the time of injury. Both took AndroGel in roughly about the same time period (Cribbs: March 2010 through April 2014; Martina: March 2012 through January 2014). Both took AndroGel at a time when AbbVie aired direct-to-consumer AndroGel

⁸ The Court will recall that not only was the pool of 100 representative in that it was randomized, but data regarding that pool was used to test the representativeness of the 32 during the process of proposing and selecting the 8 trial bellwethers. AbbVie Proposal at 2-7 (Doc. No. 1406).

⁹ AbbVie Proposal at 17; PSC Proposal at 33 (Doc. No. 1407).

¹⁰ AbbVie Proposal at 17; PSC Proposal at 37.

¹¹ AbbVie Proposal at 18; PSC Proposal at 38.

¹² AbbVie Proposal at 19; PSC Proposal at 25.

¹³ AbbVie Proposal at 19-20: PSC Proposal at 27-28.

¹⁴ AbbVie Proposal at 21; PSC Proposal at 34-35.

¹⁵ Responding to the Court's query last week, there were 63 CV cases in the original pool of 100.

advertisements. AbbVie initially did not propose Martina because of difficulties securing the deposition of a second prescriber, and because Mr. Martina alleged two different kinds of injuries. The PSC objected to inclusion of Mr. Martina because there was "no lasting damage from his MI and stroke," and because he failed to follow up with his endocrinologist for testosterone level monitoring while on AndroGel. These objections, however, should not disqualify Mr. Martina from consideration as a replacement bellwether for the *Cribbs* case. Several Plaintiffs in the bellwether pool failed to follow medical advice, and several have missing testosterone levels. For example, Mr. Myers, a bellwether trial pick, left the emergency room against medical advice at the time of his pulmonary embolism (PE), and his medical records are missing a number of early testosterone levels. The PSC nevertheless advocated for the inclusion of the *Myers* case in the trial pool, saying it is "representative of the larger pool of cases." PSC Proposal at 23.

Joe Trusty (No. 15-cv-01015): Mr. Trusty used AndroGel 1.0% from November 2008 through August 2013. Neither side chose this case initially because Mr. Trusty alleges a "chest pain" injury. There are approximately 49 such non-MI AbbVie-only cases. In addition, AbbVie believes it is likely that this case is subject to a statute of limitations defense. As a result, AbbVie acknowledges it is not as representative as other cases that were included in the first trial pool.

David Deel (No. 14-cv-10435): The PSC previously proposed this as their first CV pick. AbbVie objected because Mr. Deel allegedly used Androderm in 2008, making this a mixed-use case. He was prescribed AndroGel 1.0% from August 2008 until October 2012, and AndroGel 1.62% from October 2012 through December 2013. He suffered an MI in January 2014, which he attributes to AndroGel use.

The PSC has informed AbbVie that Deel is the only already-discovered CV case the PSC proposes to add to the trial slate. AbbVie continues to object on the grounds that this is a mixed-

use case and the parties have not yet developed a proposed protocol for these cases. The PSC apparently is under the belief that this Court has already accepted Mr. Deel's case as a replacement for *Cribbs*. It is AbbVie's view that the PSC are mistaken. Mr. Deel was identified as a replacement only if the PSC was unable to get sales representative discovery in *Cribbs*. Of course, the PSC got that discovery, and *Cribbs* remained in the trial pool until this Court dismissed the case for lack of an admissible medical causation opinion.

Gene Dial (No. 1:15-cv-02190): Mr. Dial allegedly used AndroGel 1.62% from June 2012 until a heart attack caused his death in March 2013. Both parties initially did not choose the case because Mr. Dial is deceased. AbbVie also did not choose this case because it involves novel issues of West Virginia law. There are 47 cases in the AbbVie-only pool that appear to implicate West Virginia law. The PSC objected to Mr. Dial's inclusion because he had a significant testosterone deficiency that likely required lifelong testosterone therapy. That Mr. Dial likely had "classical hypogonadism" makes his case no different than the *Rowley* VTE case this Court picked for trial.

VTE Cases

AbbVie proposes **Dale Shepherd** (No. 1:15-cv-00404) as a replacement for the dismissed *Garcia* case. Both cases involve a claimed DVT injury; the current trial pool has only one other DVT case (*Rowley*) (excluding the outlier cases that both parties previously identified). Mr. Shepherd allegedly used AndroGel 1.0% from February 2011 to September 2011. The PSC objected to the inclusion of this case because Mr. Shepherd allegedly has serious psychological issues, but these issues, if not related to his claims, would not come up at trial, and even if related, would be the proper subject of a limiting instruction. The PSC further objected because Mr. Shepherd had "more than the average number of confounding physical ailments," PSC Proposal at 37, but a belief that a Plaintiff has a number of potential alternative explanations for his DVT

does not render his case non-representative, particularly because DVTs have many known and unknown causes.

AbbVie believes there are two other candidates for inclusion in the trial pool, although neither case alleges a DVT injury:

Theodore Diesslin (No. 14-cv-01086): Mr. Diesslin was prescribed AndroGel 1.0% from August 2011 to July 2012 and AndroGel 1.62% from July 2012 to September 2012. He experienced a PE on September 2012 at the age of 52. Neither side chose this case in the initial selection because Mr. Diesslin alleges his PE caused him to develop a fainting disorder that ultimately required placement of a pacemaker. The PSC also object to the inclusion of Mr. Diesslin because he is a Texas resident, making it likely that Texas substantive law applies. There are 373 other Texas residents in the AbbVie-only pool.

Michael Romanik (No. 1:14-cv-08202): Mr. Romanik was prescribed AndroGel 1.62% from July 2011 to April 2012, when he suffered a PE. He was 46. Neither side chose this case in the initial selection because Mr. Romanik has nephrotic syndrome, and neither side was able to depose the prescribing and treating physicians. AbbVie does not believe Mr. Romanik's nephrotic syndrome to be a disqualifying fact, but acknowledges that the difficulties obtaining discovery may persist if this case is chosen.

III. The PSC's one-sided selection proposal is wasteful, unworkable, and unfairly skews the bellwether trial pool.

AbbVie understands the PSC's position to be that they should choose all bellwether replenishment cases, with no input from AbbVie. As mentioned above, the PSC intends to select *Deel*, a mixed-use MI case brought by a plaintiff who was prescribed both AndroGel and Androderm and to select an as yet unidentified VTE case from the existing pool. The PSC otherwise wants to hand-select six completely fresh cases, believing they can be fully discovered,

briefed, and ready for trial by the end of the year. This flawed proposal is wasteful, doomed to lead to delay, and unlikely to equally inform both parties.

First, the PSC's proposal is obviously unfair and would dramatically skew the composition of the trial pool. If accepted, the remaining pool of eight trial picks would consist of six PSC selections (including Konrad, which both sides chose). And if the Court accepts the PSC's suggestion to replenish with six PSC-selected cases, the disparity grows larger. These picks are more likely to involve claimed injuries and/or unique social factors intended to incite large verdicts, and therefore will likely be less representative and informative. See Standards and Best Practices for Large and Mass-Tort MDLs, Duke Ctr. for Judicial Studies 29 (2014) ("[S]ome judges have been critical of allowing the parties too much freedom to select cases because advocates may have a strong inclination to pick cases they are most likely to win, without regard to the representativeness of those cases."). This would be an unprecedented and unwarranted result. For good reason, MDL judges do not allow one side to choose all of the cases to be tested in the bellwether process. See, e.g., In re Vioxx Prod. Liab. Litig., 501 F. Supp. 2d 789, 791 (E.D. La. 2007) (both sides permitted an equal number of bellwether selections for trial); Fallon, Bellwether Trials in Multidistrict Litigation, 82 Tul. L. Rev. 2323, 2350 (2008) (Judge Fallon, presiding over the In re Vioxx MDL, noted that "permitting only one side to fill the entire trialselection pool ... opens the door for the inequitable stacking of overtly unfavorable and possibly unrepresentative cases.").

From the beginning of this process, the Court has been mindful that unfettered attorney selection "incentivizes picking cases on the far ends," as both sides choose cases they think are the strongest for their respective positions. Aug. 18, 2015 Hearing Tr. at 68:1-6; *see also* July 9, 2015 Hearing Tr. at 14:4-8 (case selection "is not supposed to be a process where the plaintiffs pick the

really great cases and the defendants pick the dogs. It's a complete waste of time if that happens, and I am not going to permit that."). The Court has aimed to "ensure fairness to all parties" and to "maximize the likelihood that the bellwether selection and trial process will be both representative and productive." Amended CMO No. 14, at 1 (Doc. No. 793). Allowing one side to choose all bellwether cases will subvert both goals.

Further, as has become abundantly clear, the parties do not start on equal footing in the bellwether cases. Plaintiffs know far more about their clients and individual cases. AbbVie obtains only an inaccurate and incomplete Plaintiff Fact Sheet, which will undoubtedly be corrected once or more over the course of discovery, as occurred with the first bellwether group. If fortunate, AbbVie may also get a Plaintiff-selected collection of limited medical records, but even that information is missing in almost 1/3 of cases and substantially incomplete as to all cases. Allowing the PSC the added advantage of selecting *every* replacement case amplifies the unfairness of this knowledge gap; the PSC will have a much better understanding at the time of selection as to the strengths and weaknesses of the case.

The most logical explanation for the PSC's proposal that the Court reverse course is apparent from the face of the proposal—it is designed to be punitive. And the PSC has confirmed this, contending that it is warranted by AbbVie's purported "gamesmanship." The PSC now blames AbbVie for the loss of *Cribbs* and *Garcia* from the trial pool. The PSC is wrong. The Court recognized the "error came up on the plaintiffs' side" in *Garcia*. May 18 Hearing Tr. at 20. That case stayed in the bellwether pool even after discovery made clear that Mr. Garcia's claims had no factual support because the plaintiffs refused to acknowledge it should be dismissed until forced to present a supporting expert report. This Court dismissed *Cribbs* on summary judgment

 $^{^{16}}$ At last count, Plaintiffs' counsel have produced fewer than 100 pages of medical records in 985 of 3511 AbbVie-only cases.

after the Plaintiffs' expert failed to satisfy *Daubert*. There was no way AbbVie could have "gamed" that case to develop the way it did.

More practically, if the Court were to accept the PSC's selection proposal, we would lose the benefit of the discovery done to date in most if not all of the discovery bellwethers, which took months to complete at great expense to the parties. This process provided valuable information and identified the cases with a higher probability of testing cross-cutting issues. Equally important, these cases are developed enough that it will be realistic for the parties to complete discovery and be trial-ready in a year, when the current pool of trial picks will have been exhausted. The PSC's proposal, on the other hand, ignores the history of this litigation. Despite the best efforts and diligence of the parties, after a two or three month record-collection period, core discovery of the initial bellwether pool took almost seven months, followed by seven months of additional fact and expert discovery in the trial-selected cases. The Court recognized last week that a similar process would have to take place here if the parties were to start with a new group of cases. May 18 Hearing Tr. at 23-24. The Court also recognized this would be a "work-intensive undertaking" that would be unlikely to get done within the Court's desired time frame. Id. That there are fewer cases to work up in this proposed second round leads only to modest time savings. Examining six cases, collecting, producing, and reviewing medical records and sales representative files will once again take months. The parties then need to identify and depose a slate of treating physicians, and presumably the PSC will want to depose a sales representative. Even estimating conservatively, and based on prior experience in this litigation, assuming six cases are chosen there will be at least 30 depositions, ¹⁷ followed by approximately 3 months of expert discovery plus case-specific dispositive motion practice. If history is a guide, there also is a high likelihood that several if not

 $^{^{17}}$ In the 8 trial-selected cases, the parties took 50 depositions (including company sales representatives).

all of the PSC's proposed new cases will turn out to be non-viable as bellwethers, either because

they are outliers or because complications such as missing documents or witnesses make timely

completion of discovery impossible. These disqualifying facts may not become apparent to the

parties for months, at which time it will be impossible to slot another case into the pool for

discovery and trial. Given these realities, it simply is not feasible to begin and complete all of this

discovery for new cases, conduct the 6-8 depositions likely needed to finish discovery in *Deel* and

the depositions needed in an additional VTE case, and at the same time try bellwether cases in the

MDL and state courts. Delay is inevitable.

AbbVie appreciates the Court's concern that there may not be sufficient cases remaining

in the discovery pool. But the solution is not to allow one side to cherry-pick a handful of cases

for discovery. Rather, if the Court wishes to replenish the larger discovery pool—which AbbVie

believes is not necessary at this time—the solution is to employ the same rigorous process that the

parties used before, first choosing cases at random from the already-selected random pool of 100

cases, and then after a limited period of time to exclude those that are facially disqualified, using

some method to select the cases that will be discovered and worked up for trial. The Court has

already tried the attorney selection method, and according to the PSC, it led to a pool of mostly

outlier cases. AbbVie believes that simple random selection could do just as well, and would

alleviate any concern of "gamesmanship" by either side. The parties could run the remaining cases

in the initial 100-case pool through randomizer.org a second time and generate six new candidates

for inclusion in the bellwether program.

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Respectfully submitted,

/s/ Trent B. Miracle

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CERTIFICATE OF SERVICE

I hereby certify that on May 22, 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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