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 Hon. Judge Matthew F. Kennelly

JOINT STATUS REPORT
FOR JULY 20, 2015 CASE MANAGEMENT CONFERENCE

In accordance with the Court's instructions at the July 9, 2015 case management conference ("CMC"), the Plaintiffs' Steering Committee (the "PSC") and Defendants AbbVie Inc. and Abbott Laboratories (collectively, "AbbVie") jointly submit this report regarding the status of the parties' discussions, agreements and disagreements on the following three topics to be addressed at the CMC scheduled for July 20, 2015:

I. Production of AbbVie Custodial Files

A. Plaintiffs' Position

1. Brief Summary of Background: Following the completion of the parties' extended negotiations on search terms and a de-duplication protocol to minimize the review and production burdens associated with custodial productions, the PSC requested on June 4th that the negotiated search protocol be run against the custodial collections of 79 current and former employees (9 of which had been requested in November), as well as against the documents swept or collected in *King v. Solvay*. The PSC was later advised that its supplemental request for documents collected in *King v. Solvay* implicated an additional 72 custodians. The PSC's June 4th request was thus characterized as a request for 151 custodial files.

The custodians selected by the PSC were a small subset of several hundred potential AbbVie employees based on information identified through AbbVie corporate organizational charts, a Fed. R. Civ. P. 30(b)(6) deposition regarding corporate structure, and Plaintiffs' investigation. The PSC has not asked for—and will *not* ask for—the custodial files of every AbbVie employee with information concerning AndroGel. Supplemental custodial requests will be driven by review of the presently requested custodial files and prospective depositions. Among other complicating factors in this litigation, the PSC believed that its request was reasonable and anticipated by AbbVie given the following circumstances:

(a) the claims against AbbVie involve multiple formulations of AndroGel, marketed for 15 years (and developed for years before that), reflecting the efforts of hundreds of AbbVie custodians;

(b) the breadth of injuries and number of cases against AbbVie in this MDL;

(c) the fact that the parties compromised on a specific production framework to streamline responsive documents and minimize duplication; and

(d) the specific requirements of CMO No. 13 (to certify completed production of requested custodial files within 45 days of request).

Pursuant to AbbVie's request, the PSC prioritized or "tiered" the custodians that Plaintiffs wanted produced first. The PSC's request for the 79 custodians was tiered as follows: 34 in Tier A, 24 in Tier B, and 21 in Tier C. The tiering that the PSC provided was designed to include a small number of custodians from each of the major topic areas in each tier (*e.g.*, clinical, non-clinical, regulatory, marketing, pharmacovigilance, epidemiology, and other relevant departments) in order to allow the PSC to "get the lay of the land" before focusing more deeply in a given topic area of discovery.

Half of the 34 Tier A custodians overlap with the 23 custodians that AbbVie identified in their initial disclosures (the remaining six custodians initially identified by AbbVie were split in the PSC's Tier B and C). AbbVie has started to produce files for the 23 custodians it identified

(based on the Cook County search terms), but, while there is significant overlap, the parties do not agree on which custodial files should be produced first.

AbbVie has only completed the production of one custodial file (Pablo Hernandez), which was completed on July 10. (Mr. Hernandez's file consists of 2.6 million pages—more than 1.7 million of which was received on July 10th, and all subsequent productions will be "de-duped" against this and the other files produced to date.) Notably, Mr. Hernandez's file was produced first because his deposition was requested by the Cook County plaintiffs and AbbVie's counsel asked the PSC if we would work with them to cooperate on this deposition. In order to be cooperative, the PSC agreed despite the fact that we did not have Mr. Hernandez's file and that Mr. Hernandez would not have been the deposition we took as the first deposition in the case were it not for AbbVie's request. From discussions with AbbVie, AbbVie has not even collected documents from all the 34 Tier A custodians. AbbVie has advised the PSC that it plans to object to a small number of the 79 requested custodians based on relevance, but, in the weeks since this dispute arose, it has not yet identified any such objection.

The parties have engaged in several telephonic and in-person meet and confers on this topic, both before filing opening submissions on June 29 and responses on July 5, and after the July 9 CMC. Unfortunately, no agreement resulted from these meetings. During the parties' discussions, AbbVie no longer insisted on a "cap" on the number of custodial files, but it has not agreed to a production timeline. AbbVie has made no commitment to a timeline, except to estimate that production of the 33 remaining Tier A custodians would not be completed until October or November 2015, even though AbbVie has partially produced 16 of those custodians using the Cook County search terms. In addition to this unnecessary delay, AbbVie still insists that the PSC should identify its deposition witnesses based only on the discovery to date, and that AbbVie

should only have to produce the custodial files for those witnesses before a deposition begins. However, the PSC requires, at a minimum, the 34 Tier A custodial files before picking deposition witnesses and starting to take depositions.

2. Plaintiffs' Proposal: With the Court's comments from the July 9 CMC in mind, the PSC makes the following proposal:

- Tier A Custodians shall be produced on a bi-weekly rolling basis, with production of the remaining 33 Tier A custodians completed by September 30, 2015, with depositions starting in October (the PSC will likely choose Tier A custodians as initial deposition witnesses, but it cannot make that determination until their documents are received).

- Tier B & C Custodians shall be produced on a bi-weekly rolling basis, with productions staggered 45 days between tiers. Assuming Tier A is to be produced by September 30, 2015, Tier B would be produced in bi-weekly rolling productions to be completed by November 14, 2015, and Tier C would be produced in bi-weekly rolling production completed by December 29, 2015.[1]

- If AbbVie has a relevancy-based objection to a specific custodian, the PSC is prepared to discuss and resolve any such objection in short order.

- The PSC is withdrawing its request to AbbVie for the supplemental search and production of the *King v. Solvay* materials, which implicated 72 custodians.

B. AbbVie's Position

AbbVie and Plaintiffs have had extended discussions, in person and telephonically, on July 11, 15, and 16, regarding how many custodial files should be produced and how custodial productions should be managed consistent with the schedule for bellwether trials. AbbVie asks the Court to enter an order consistent with the following:

[1] This proposal significantly expands the time limits set forth in CMO No. 13, which requires custodial file productions to be completed 45 days after request. The 79 custodians now at issue were requested June 4, 2015 (and 9 of these were requested in November 2014). As such, notwithstanding the mandates of CMO No. 13, this proposal will afford AbbVie over six months to produce these custodial files.

1. AbbVie will not be required to re-produce the 72 King/Solvay custodial files using MDL search terms. If Plaintiffs wish to request that a particular witness's file from the King/Solvay production be produced using MDL terms they may do so, subject to the limits set forth below and the reasonable availability of those files.

2. Production of custodial files will be capped at 65 (which is slightly more than 1.5x the number of deponents). This would include any files from the Solvay/King period, as referenced in item 1, and the Pablo Hernandez file already produced.

3. Following production and review of the 65 files, Plaintiffs may request up to 10 additional custodians' files focused on discrete, limited topics not already reasonably covered by others, with a showing of good cause. AbbVie would not oppose the additional production on the basis of burden though AbbVie reserves the right to challenge good cause, as well as lack of relevance or some other substantive ground.

5. To facilitate both custodial file production and depositions, Plaintiffs will provide AbbVie, by July 30, 2015, a list of the 10 people they want to depose first and whose files, therefore, should be prioritized for production. (Subject to agreement with Cook County, AbbVie will not object if Plaintiffs no longer wish to prioritize Pablo Hernandez for production among the first 10 witnesses.) If requested to assist with deposition preparation, AbbVie will endeavor to prioritize productions by business area.

6. To assist AbbVie in reserving time for depositions on witness' calendars, Plaintiffs will also provide AbbVie, by August 12, 2015, with a proposed time frame for starting the first 10 depositions as well as any dates (in coordination with other state Plaintiffs).

7. In furtherance of the Court's CMO setting a limit on the number of depositions to be taken of each defendant, depositions noticed in state court cases and cross noticed in the MDL

will count against those limits if MDL Plaintiffs elect to conduct their own examination of the witness. However, if a deposition is cross noticed in the MDL and MDL Plaintiffs choose to forgo conducting their own examination, then MDL Plaintiffs shall not notice the same witness for another deposition. The parties are reminded to maximize coordination with the state court cases so that duplicative discovery is minimized.

II. Plaintiffs' Request for Entry of a Defense Fact Sheet and Protocol for Same

A. Plaintiffs' Position

The parties have met and conferred in-person and telephonically during the past week to try and reach agreement on the DFS. While it appears many issues are close to resolution, with compromise by both sides, the largest and still unresolved issue concerns production of the sales call notes, which the PSC believes are maintained in a readily accessible database.

The relevance of call notes is not questioned by AbbVie, and, indeed, they are some of the most relevant and probative information available in litigations of this type. The claims at issue in this litigation, including those implicating off-label marketing and fraud, are expected to be heavily dependent on call notes. The call notes will describe the conversations and communications by and between AbbVie drug sales representatives and the thousands of doctors that prescribed AndroGel. In addition to the merits, knowing what was (or was not) said by AbbVie, what was asked by doctors and what was included or omitted in AbbVie's responses is important to know which cases are representative for purposes of bellwether selection.

This MDL involves extraordinary allegations regarding the invention of a fake disease by the marketing department and the subsequent promotion by sales representatives of that off-label use. These claims are, in many respects, dependent on the content of the communications made to the physicians who prescribed the drug. The Plaintiffs' claims for negligent misrepresentation

and fraud survived the motion to dismiss based on allegations in the complaint that will require evidence from the call notes. Among the other allegations in this MDL, the call notes are relevant to the allegation that, because there is no proof of efficacy for the off-label uses, any risk of harm would be unacceptable. Therefore, in order to find representative cases for the purpose of bellwether selection, it is crucial for the plaintiffs to have access to this highly relevant and probative evidence, and not simply receive the call notes for the 32 bellwether discovery cases that will make up the pool for case-specific discovery. Knowing the content of the call notes will help guide the parties to select representative cases before the deadline on October 31, 2015.

Even though the PSC is committed to a bellwether process that will inform the parties and the Court regarding common issues in the litigation, AbbVie raises the illusory fear that allowing the PSC access to the call notes will lead to "cherry picking" salacious examples of rogue sales representative behavior. Indeed, the argument can equally be made that AbbVie might seek to select cases that have no call notes or very limited call notes. However, knowing the frequency, duration and content of call notes will better assist both sides to select representative cases. As noted in the PSC's briefing on this issue, production of call notes is routine. While AbbVie offered to “not look” at the call notes if it meant that the Plaintiffs would be deprived of that evidence, this is not a fair trade-off because it is the Plaintiffs that have the burden of proof. Understandably, Defendants wish to limit the scope of this litigation to a simple failure-to-warn claim, but the evidence already available in the public domain shows that this may be the most egregious off-label marketing and disease mongering case since the onset of multidistrict litigation.

As for any burden argument, burden is no longer really challenged, particularly in light of the Court’s observations that the redactions (absent HIPAA) are self-imposed by AbbVie, and even the HIPAA redactions, if any, can be protected by an Order of the Court. (*See* Hr’g Tr. July

9, 2015 20:19 to 23:8.) Additionally, the PSC has been willing to offer AbbVie more time to produce the call notes beyond the 30-45 days needed for the DFS, including into late September or the first week of October, so that the PSC has enough time to review them before the bellwether selections. AbbVie rejected this offer as well.

Lastly, while AbbVie submitted a proposed DFS with its surreply, the PSC has objected to AbbVie's version and respectfully requests that Court adopt the PSC's proposed version, which includes essentially the same topics and very similar questions as AbbVie's version without the significantly limited language that AbbVie included in its proposed DFS that, while seemingly similar to the PSC proposed questions, has subtle but important limitations that AbbVie included.

B. AbbVie's Position

As a result of negotiations between the parties, AbbVie understands that Plaintiffs' primary remaining objection to the AbbVie DFS is that it does not include production of call notes for all 666 cases, over potentially a 15 year time period. AbbVie is unable to agree to the production of call notes across all cases and all time periods as it constitutes a time-consuming undertaking (even after they are culled and collected, the relevant notes will have to be reviewed individually for patient confidential information and information regarding sales and marketing of entirely unrelated products) and the results should have no bearing on selecting **representative** bellwether cases. They are only possibly informative if a party is attempting to select what is perceived to be the "best" or "worst" case.

AbbVie asks the Court to enter its proposed DFS, attached to its sur-reply brief, with one additional compromise that AbbVie believes should fully address any argument that Plaintiffs may advance that they need to know more than just whether a prescribing doctor was visited by AbbVie sales representatives. That proposal is to produce a listing for each prescriber of the

actual dates of each visit and the last names of the sales representatives. This would allow the parties to see not just the YES/No fact of a sale call but also the relative number of details, relevant times, and last name of the sales representatives for the case pool.

The only purpose served by producing the details of the call notes, if any (which requires the most time to produce), is to enable plaintiffs to pick the comments that they find most advantageous to their case on the **merits**, which should not be factor in selecting **representative** bellwether cases.

III. Report on other AbbVie Discovery Responses (Timing &Process)

i. Timing of adverse event ("AE") database production; and

ii. Timing of statistical analysis system ("SAS") production.

A. Plaintiffs' Position

(i) ***Timing of AE database production***

AbbVie has told the PSC it expects to produce the AE database excerpts "at the end of September." In addition to discussing this issue at our July 15th meet-and-confer, the PSC received an email on July 16th stating AbbVie's position as follows:

> For AE production, there are several more steps involved. IT is still in the process of creating the scripts that will need to be run to remove data that will not be produced. They expect the scripts to be finalized and executed by mid August. The next step is review of narrative/case journal fields for redaction, completing that redaction and re-loading that information in the database that will be produced. Then there will be final IT steps to make sure everything is in working and acceptable order. Allowing some wiggle room for uncertainties (as are apt to happen), we are estimating production at the end of September. As I also told you yesterday, I will be in a better position to discuss deliverable with you [next week], but I believe that conversation can happen this month.

Given the importance of the AE database, how long the request has been pending, the limited number of events that are recorded in the database, and the fact that the agreement to produce it was finally made on June 12, 2015 (the day of court-ordered briefing), the PSC believes

that it should be made a priority and produced within days, not weeks. As in the case of call notes, the purported need for redaction should not be cause for delay. If any redactions are necessary, the PSC believes, based on experience in prior cases, that the determination of whether there is anything to redact and the limited redactions, if any, that will be necessary can be done quickly. Further, the PSC has been told that AbbVie has samples of this database that are available for production now, but have not been produced. The PSC respectfully submits that those samples should be produced as soon as possible.

As far as the requested call between each side's technology personnel to discuss the format in which the database will be produced, the PSC agrees with AbbVie that this conversation should occur "this month," which means it will occur within 10 days of the July 20th hearing. The PSC and its vendor will be ready to have this conversation sooner rather than later.

(ii) ***Timing for SAS production***

AbbVie has informed the PSC that it will take another month to produce the data from the statistical analytical system ("SAS"). In addition to discussing this issue at the parties' July 15th meet-and-confer, the PSC received an e-mail on July 16th stating AbbVie's position on the SAS data as follows:

> [O]ur initial review of the SAS data has shown that no redactions are necessary. We still need to review each file, but I am comfortable telling you and the court that the production will take place in August. I am aiming for August 14th.

Because there are no redactions needed and because SAS files largely consist of computer code and data points (requiring little pre-production review), the PSC does not understand why production must wait another month — until August 14, 2015. This request has been outstanding for months and it is reasonable to expect that a production should be made within a week, not another month; and, at a minimum, should be made by a date-certain.

B. AbbVie's Position:

(i) ***Timing of AE database production***

With respect to production of AbbVie's adverse event report (AER) database, the parties negotiated, at Plaintiffs' request, a unique extraction of adverse event data contained in hundreds of multi-relational tables. The unique extraction involves several steps including creating a copy of the complete database, quality assurance review, writing "scripts" to remove non-relevant information, executing those scripts, review of free text fields for redaction of patient identifying information, and final testing and review before production. The execution of the scripts to create the version of the data that will be produced is scheduled to be completed by mid-August. The next step of reviewing thousands of free text narratives and case journal notes will take a few weeks to complete and then be re-loaded into the database. Final review and quality checks will then need to be performed. Adding a few days to the estimate for unforeseen complications, AbbVie anticipates producing the adverse event data extraction between September 25th and 30th. AbbVie has agreed to have a discussion with Plaintiffs regarding the format of the deliverable before the end of July.

(i) ***Timing for SAS production***

The clinical trial SAS data is currently under review to ensure that no patient identifying information is included. Assuming little or no redaction is needed, AbbVie anticipates producing these files in one of our next two non-custodial file productions -- either July 31st or August 14th.

Dated: July 17, 2015

Respectfully submitted,

/s/ Trent B. Miracle

Trent B. Miracle
SIMMONS HANLY CONROY
One Court Street
Alton, IL 62002
Telephone: (618) 259-2222
Facsimile: (618) 259-2251
tmiracle@simmonsfirm.com

Plaintiffs' Co-Lead Counsel

Ronald Johnson, Jr.
SCHACHTER, HENDY & JOHNSON PSC
909 Wrights Summit Parkway, Suite 210
Ft. Wright, KY 41011
Phone: (859) 578-4444
Fax: (859) 578-4440
rjohnson@pschachter.com

Plaintiffs' Co-Lead Counsel

Christopher A. Seeger
SEEGER WEISS LLP
77 Water Street
New York, NY 10005
Phone: (212) 584-0700
Fax: (212) 584-0799
cseeger@seegerweiss.com

Plaintiffs' Co-Lead Counsel

David M. Bernick
DECHERT LLP
1095 Avenue of the Americas
New York, NY 10036
Tel: (212) 698-3500
Fax: (212) 698-3599
david.bernick@dechert.com

Hope S. Freiwald
DECHERT LLP
Cira Center
2929 Arch Street
Philadelphia, PA 19104
Tel: (215) 994-2514
Fax: (215) 994-2222
hope.freiwald@dechert.com

Attorney for AbbVie Inc. and Abbott Laboratories

CERTIFICATE OF SERVICE

I hereby certify that on July 17, 2015, 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.

/s/ Trent B. Miracle