IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
THIS DOCUMENT RELATES TO ALL CASES	

MEMORANDUM OF LAW IN SUPPORT OF THE PSC'S MOTION TO COMPEL DISCOVERY FROM DEFENDANTS ABBVIE INC. AND ABBOTT LABORATORIES

The Plaintiffs' Steering Committee ("PSC") respectfully submits this Memorandum of Law in Support of its first Motion to Compel Discovery from Defendants AbbVie Inc. and Abbott Laboratories (collectively, "AbbVie").

Respectfully submitted this 16th day of January, 2015.

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I. INTRODUCTION

As discussed at the Case Management Conference held on January 13, 2015, this is the first of several motions to compel that the PSC expects to file in the coming months. The PSC brings this motion as a result of AbbVie's delay in providing complete and proper responses to the PSC's First Request for the Production of Documents (Ex. 1.) and First Set of Interrogatories (Ex. 2.), which were both served on August 18, 2014. After an extensive meet and confer process,[1] which is still ongoing with respect to several discovery deficiencies not at issue in this motion, the PSC intends to raise discovery disputes with AbbVie in a series of motions on discrete issues that hopefully will be more manageable for the Court and the parties than an omnibus motion.[2]

In the present motion, the PSC seeks an order compelling AbbVie to produce documents and answer interrogatories in three distinct areas:

1) Copies of documents produced and transcripts of the depositions taken in *United States ex rel. King v. Solvay S.A.*, No. H-06-2662 (S.D. Tex.) (the "*King* Documents"). *King* involves AbbVie's "aggressive off-label marketing and kickback schemes" relating to AndroGel and two other drugs. AndroGel-related documents produced in *King* are plainly relevant to the issues in this case. AbbVie has agreed to produce these documents, subject to certain conditions that are unworkable and lack any legal justification. The PSC has been asking for the *King* production since April 2014. *See* April 29, 2014 Canty Email (Ex. 12), and May 6, 2014 Johnson Email (Ex. 13). It is high time these documents were produced.

[1] *See* Declaration of Seth A. Katz and Certification of Counsel Pursuant to L.R.37.2, Ex. 5 ("Katz Decl.").

[2] Additionally, the Court's rulings on the present motion may help guide the parties in their continuing efforts to resolve the remaining discovery disputes, which in turn may limit the number and/or scope of the discovery motions.

2) A copy of the entire AndroGel adverse event database. During an in-person meeting on January 12, 2015, AbbVie stated that it refuses to produce adverse event information for adverse events that are not of the type alleged in complaints filed in this litigation. *See* Katz Decl. (Ex. 5) at ¶10. As explained in detail herein, this position is contrary to law. Plaintiffs are entitled to conduct their own analysis of all adverse events that have occurred in patients taking AndroGel. Plaintiffs should be able to evaluate, for example, the manner in which each adverse event was classified, the relative frequency with which different types of adverse events were reported, and the timing of those reports. This information is indisputably relevant because it bears directly on when AbbVie had notice regarding the nature of the adverse events caused by its drug. This is the fundamental "***what they knew and when***" information that is at the center of the failure-to-warn and negligence claims in this case. As such, there is no reasonable argument that the entire adverse event database should not produced without further delay.

(iii) Responses to several of the PSC's Interrogatories that AbbVie answered by impermissibly invoking Federal Rule of Civil Procedure 33(d) without identifying the documents that contain responsive information with the specificity required by the Rule. AbbVie has responded in this manner to 64 of the PSC's 100 Interrogatories. The majority of these responses state that "pursuant to Rule 33(d), information responsive to this Interrogatory will be produced."[3] The pervasiveness of these "Rule 33(d) responses," combined with the staggeringly small volume of documents that have been produced to date, constitutes an egregious abuse of the discovery process. The PSC respectfully requests that the Court issue an Order compelling proper responses to these Interrogatories. An Order making clear that this conduct will not be tolerated may go a long way toward preventing this type of abuse in the future.

[3] *See, e.g.*, AbbVie's Interrogatory Response No. 10., Ex. 4 at 17.

II. EFFORTS TO RESOLVE THESE DISPUTES WITHOUT COURT INTERVENTION

As required by the stipulated terms of CMO No. 13, AbbVie served its Reponses to the PSC's First Request for the Production of Documents ("AbbVie's RFP Responses") (Ex. 3.) and its Responses to the PSC's First Set of Interrogatories ("AbbVie's Interrogatory Reponses") (Ex. 4.) (collectively, the "Responses") on November 15, 2014. In addition to boilerplate objections and other deficiencies, AbbVie's RFP Responses repeatedly include the statement that it will produce documents "subject to clarification and a meet and confer regarding the scope" of the PSC's requests.[4] AbbVie's Interrogatory Responses repeatedly include a similar statement that "AbbVie also seeks clarification on the information requested in this Interrogatory and the scope of the request."[5] In practice, these innocent-sounding requests for clarification have resulted in unacceptable delays in the production of documents and substantive interrogatory responses.

Furthermore, AbbVie responded to the majority of Interrogatories by stating that responsive information "will appear in documents to be produced," in violation of Fed. R. Civ. P. 33(d). The PSC outlined these deficiencies in a lengthy letter sent to initiate the meet and confer process on November 25, 2014. *See* PSC's November 25, 2014 letter (Ex. 6). This letter was followed by phone conversations on December 5, 2014 and December 12, 2014. Katz Decl. (Ex. 5), at ¶ 4. Additionally, the parties exchanged a series of letters over the following weeks. *See* PSC's December 15, 2014 Letter (Ex. 7); AbbVie's December 22, 2014 Letter (Ex. 8);

[4] *See, e.g.*, AbbVie's RFP Response No. 12, which objects to requests for documents that relate to adverse events related to AndroGel but states that AbbVie will produce responsive documents "subject to clarification and a meet and confer regarding the scope of this Request." (Ex. 3 at 13.)

[5] *See, e.g.*, AbbVie's Interrogatory Response No. 29. (Ex. 4 at 32-33.)

PSC's December 22, 2014 letter (Ex. 9); PSC's December 23, 2014 Letter (Ex. 10); and AbbVie's December 30, 2014 Letter (Ex. 11).

Most recently, representatives of the PSC met with AbbVie's counsel in Chicago on January 12, 2015, in the spirit of cooperation and with the hope that providing the requested clarification would move the PSC closer to receiving complete and proper discovery responses. (Katz Decl. (Ex. 5), at ¶8.) The meeting lasted close to four hours, stretching past 7:00 p.m. The PSC's representatives were willing and available to continue the meeting for as long as necessary to allow AbbVie whatever time it would need to obtain the clarification it claims it needs to begin responding to the PSC's Requests.[6] Unfortunately, even after having the opportunity to ask for clarification, AbbVie did not make any assurances that the requested materials will be produced.[7] The PSC remains open to discussions that would allow the parties to resolve some or all of these issues even while this motion is pending.[8] At a point, however, the time for meeting and conferring must come to an end. With regard to the items requested in this Motion, that time has passed.

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[6] The PSC respectfully submits that its Requests are clearly stated and easily understood by a sophisticated pharmaceutical company and their counsel. One example of AbbVie's unreasonable requests for clarification is regarding the PSC's request for "all documents that relate to any test, study, preclinical or clinical trial" concerning AndroGel. *See* AbbVie's RFP Response No. 18 (Ex. 3), at 15. This request is very specific. Furthermore, it strains credulity that a sophisticated pharmaceutical company would not have a working understanding of what is meant by "tests, studies, preclinical and clinical trials" that relate to its drug.

[7] In fact, at the January 12, 2015 in-person meeting, AbbVie's counsel described several items that it would ***not*** be producing rather than what it would produce. If the parties cannot resolve these issues, they will likely result in additional motions to compel.

[8] During the in-person meeting on January 12, 2015, the PSC's representatives offered to meet again in roughly two weeks to continue the conversation. Although no meeting has yet been scheduled, the PSC remains willing to continue with in-person and telephonic meetings as long as they are productive.

Under the guise of seeking clarification, AbbVie has attempted to invert the discovery process and pursue impermissible delay. AbbVie appears to expect the PSC to explain what information it thinks will be sufficient to respond to each discovery request. However, AbbVie is the party with knowledge about what information is available, which custodians possess responsive documents and how discovery materials are organized and stored. It is not the PSC's burden to explain to AbbVie and its experienced defense counsel what it ought to be looking for and where it might be found.

It has also become clear that AbbVie's requests for more time to investigate whether it has responsive information within its possession are hollow attempts to delay these proceedings. AbbVie has been on notice of this litigation for quite some time. These cases were first filed in the Northern District of Illinois in February 2014, and the coordinated AndroGel litigation has been pending in this Court since March 14, 2014, so AbbVie has had ten months to conduct its investigation and should be ordered to begin producing these materials.

The PSC's Requests for Production were served on August 18, 2014, and AbbVie's Responses were served on November 15, 2014, but AbbVie has only just begun to take steps to identify fundamental sources of information in its possession. For example, AbbVie delayed taking steps to evaluate its adverse event database, which is critical for the claims and defenses at issue in this litigation. *See* AbbVie's Dec. 22, 2014 Letter (Ex. 8), at 2 ("we are going to evaluate the database after the first of the year, and hope to be able to make a proposal that will reasonably address all of the Parties' concerns"). Furthermore, AbbVie's self-serving claims that the companies and their counsel are working "in good faith and as diligently as reasonably possible" (Ex. 8, at 1) to respond to PSC's Requests are contradicted by the lack of substantive

responses to date and the parties' inability to make much headway toward resolving even the most basic discovery disputes.[9]

Despite exhaustive efforts by the PSC to meet and confer regarding the substantial deficiencies in AbbVie's discovery responses, AbbVie has only provided substantive responses to 13 of the PSC's Interrogatories. *See* AbbVie's Interrogatory Responses Nos. 1, 2, 3, 9, 18, 67, 76, 78, 80, 82, 83, 88, and 90 (Ex. 4). This is woefully inadequate given the time that this litigation has been pending and the five months that AbbVie has had to respond to these Interrogatories.

Despite the PSC's good faith efforts to resolve the discovery differences at issue in this motion, the minimal progress we have made to date makes it is clear that the Court's involvement may be useful. The three categories of discovery requested are so indisputably relevant that we should not have to take up the Court's time with this motion. It is past time for AbbVie to begin producing this information. Therefore, the PSC respectfully requests that Court enter an Order requiring AbbVie to produce the requested information within 15 days of the Court's Order.

III. LEGAL STANDARD

Rule 37(a) of the Federal Rules of Civil Procedure provides, in pertinent part, that:

> ... A party seeking discovery may move for an order compelling an answer, designation, production, or inspection. This motion may be made if:
>
> …

[9] Production of the documents and responses requested in this Motion does not require AbbVie to run searches using the search terms that have been the subject of extensive negotiation between the parties because the search terms are only going to be applied to custodial files and will not be used to identify documents from other data sources such as public storage areas/drives, sharepoints and e-rooms. Therefore, the lack of an agreement on search terms does not preclude AbbVie from producing the requested information without further delay.

> (iii) a party fails to answer an interrogatory submitted under Rule 33; or
>
> (iv) a party fails to respond that inspection will be permitted--or fails to permit inspection--as requested under Rule 34.
>
> … [A]n evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond.
>
> Fed. R. Civ. P. 37(a).

The Federal Rules grant the district court significant discretion in ruling on a motion to compel. *Gile v. United Airlines, Inc.*, 95 F.3d 492, 495-6 (7th Cir. 1996) (*citing* Fed. R. Civ. P. 34(b), 26(a)).

The scope of discovery under the Federal Rules is broad. Parties may obtain discovery regarding "any nonprivileged matter that is relevant to any party's claim or defense[.]" Fed. R. Civ. P. 26(b)(1). "Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *Id.* "The federal discovery rules are liberal in order to assist in the preparation for trial and settlement of litigated disputes." *1221122 Ont. Ltd. v. TCP Water Solutions, Inc.*, 2011 U.S. Dist. LEXIS 67401, at *5 (N.D. Ill. June 23, 2011). The Federal Rules provide that a party may request production of "any designated documents or electronically stored information" from another party, so long as those documents are "reasonably calculated to lead to the discovery of admissible evidence." *Gile*, 95 F.3d at 495 (*citing* Fed. R. Civ. P. 26 (a), 34(b)).

IV. ARGUMENT

A. *KING* DOCUMENTS

The PSC's Document Requests Nos. 1 and 2 seek documents related to AndroGel that were produced by any party in *United States ex rel. King v. Solvay S.A., et al.*, No. H-06-2662 (S.D. Tex.), and transcripts of the depositions taken in *King*. Before formation of the MDL, attorneys, who have since been appointed as members of the PSC, initially requested that the

King Documents be produced in April 2014. *See* April 29, 2014 Canty Email (Ex. 12), and May 6, 2014 Johnson Email (Ex. 13).

The *King* case is a *qui tam* action brought on behalf of the United States and several states to recover treble damages for fraudulent claims to the Government by AbbVie. The case involves allegations of AbbVie's "aggressive off-label marketing and kickback schemes" relating to AndroGel and two other drugs. The complaint alleges that "to expand and maintain its market share of these drugs, Solvay[10] deliberately and deceptively marketed uses that had not been approved by [the FDA], doled out kickbacks to doctors in exchange for prescriptions, and trained doctors to misstate diagnoses so that… federal healthcare programs would approve and pay for unapproved uses." *King* Fifth Amended Complaint Excerpt (Ex. 14), at ¶ 1. Accordingly, there is substantial overlap between the issues and the documents requested in that action and those relevant in this MDL. *See* Excerpts of Plaintiff's Requests for Production in *King* (Ex. 15), ¶¶ C.1 – C.85, p. 28-38. There is no reasonable argument that AndroGel documents produced by AbbVie in *King* are not relevant or discoverable in this litigation. AbbVie agrees that the *King* "matter bears on AndroGel allegations that are substantially similar to this Litigation th[r]ough the time period of 2008." AbbVie Letter dated Dec. 22, 2014 (Ex. 8), at 3.

During a phone conversation on December 12, 2014, AbbVie's counsel reported that the company would produce all *King* documents that are related to AndroGel and relevant in this litigation, and that production would begin towards the end of January 2015. Katz Decl. (Ex. 5), at ¶ 8. Subsequently, in a letter dated December 22, 2014, AbbVie unreasonably conditioned

[10] Solvay's pharmaceuticals business, including the AndroGel product, was acquired by Abbott Laboratories in 2010. Solvay marketed and sold AndroGel in the United States between approximately 1999 and 2010.

this production for the first time on the PSC's agreement that it need not search large swaths of otherwise discoverable ESI for responsive material. AbbVie Letter dated Dec. 22, 2014 (Ex. 8) at 3. AbbVie asks the PSC to agree that its production in the *King* matter will "satisfy [PSC's Document Requests] through the 2008 time period,[11] except for currently active [ESI]." *Id.*

AbbVie has at least three sources of ESI which may contain unique, relevant data predating 2008. The first is "currently active" data, held by now-AbbVie employees or systems that were once Solvay employees or systems, and which survived first the Solvay-Abbott merger and then the Abbott-AbbVie spinoff. AbbVie acknowledges its obligation to search that data for responsive material, and has agreed to do so.

Another source of relevant ESI predating 2008 is a cache of several thousand backup tapes containing Solvay data. Plaintiffs do not yet know what they contain. At a Rule 30(b)(6) deposition, Plaintiffs asked AbbVie's "Director and Senior Counsel, eDiscovery and Records Management" (Mathew Gasaway), and found that AbbVie does not know this yet, either. Gasaway Tr. (Ex. 16), at 101:20-102:6. Plaintiffs did learn that, in connection with the *King* matter, some of these backup tapes were restored. *Id.* at 220:17-221:18. This is a strong indicator that the backup tapes contain unique, relevant data not found in the "active" source described above or the "legal hold" source described below, and that further restoration efforts will likely be necessary in this case. If AbbVie has not yet begun that process, and if AbbVie truly does not yet even know what is on the tapes, then AbbVie is disturbingly behind schedule. AbbVie's offer of only the *King* production is conditioned on Plaintiffs' agreement to forego

[11] AbbVie has since clarified that it does not seek to limit its obligations to produce post-2008 ESI. (AbbVie Letter dated Dec. 30, 2014, Ex. 11, at 1.)

discovery from this source, even though AbbVie itself does not know what it contains. Plaintiffs cannot agree.

A third source of relevant pre-2008 ESI is "legal hold" data: ESI collected by Solvay, or restored by Abbott and AbbVie over the years, for the purposes of legal holds. Gasaway Tr. (Ex. 16), at 213:1-215:7. This includes not only the *King* action, but presumably other matters from the pre-2008 time period, such as Solvay's suit against makers of generic Androgel, the FTC investigation of Solvay, any employment-related suit, and the like. Some unknown subset of this legal hold data was available for discovery in the *King* action. That subset was winnowed for review by Solvay's attorneys using unknown search methodologies. That even smaller group of documents was undoubtedly then reviewed for, *inter alia,* relevance, using criteria specific to the *King* allegations. Then, an even smaller group of documents was produced to the *King* relators. AbbVie asks the PSC to agree that this *King* production set will fulfill their pre-2008 discovery obligations. AbbVie might as well offer a used car, sight unseen, of unspecified make, model and year. The PSC cannot agree to this.

At a Rule 30(b)(6) deposition, Plaintiffs asked Mr. Gasaway to describe the *King* production. He could not. He did not know what documents were collected or how, from what sources, or what date range was covered. *Id.* at 234:14-236:4. He also admits that he does not know whether the *King* production will serve the needs of this case. *Id.* at 214:1-10. Mr. Gasaway testified that the collected and produced documents are in the hands of Solvay's counsel in *King*, and that he has *not* requested to transfer these to AbbVie as of the date of the deposition. *Id.* at 238:20- 240:6. AbbVie has not yet seen the used car it's selling, either.

AbbVie claims that it is "not going to be restoring and/or gathering materials and custodial files twice." *Id.* But this is not what Requests for Production Nos. 1 and 2 ask

AbbVie to do. Those requests seek documents that AbbVie *has already produced* in *King*, requiring no new searches or gathering of information. AbbVie produced documents relevant to a 2006 qui tam action, and now been sued for personal injuries in claims which are inclusive of, not coextensive with, the allegations in King. The *King* Documents are relevant, non-privileged documents in AbbVie's possession, and are therefore discoverable. *See* Fed. R. Civ. P. 26 (b)(1) (parties "may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense").

There is no reasonable expectation that the *King* documents meet the search and collection criteria applicable to ESI production in this litigation. AbbVie cannot reasonably claim that its purported condition for the production of *King* documents is appropriate. The PSC is not required to accept a "pig in a poke." The reality is that, until AbbVie can identify what information was produced in the *King* litigation and how it identified what was produced, the PSC cannot evaluate whether the production is adequate for this litigation.

AbbVie has already unreasonably delayed the investigation and production of the *King* Documents, which were first requested nine months ago. AbbVie has indicated that it should be able to start production of the requested documents in late January 2015. AbbVie Letter dated Dec. 22, 2014 (Ex. 8), at 3. AbbVie should produce the documents as requested by Plaintiffs starting in late January 2015 (as it said it would in its December 22 letter), without any limitations or conditions. There is no basis to withhold this information, which is relevant, in AbbVie's possession, custody or control and that has already been produced in other litigation. Furthermore, given AbbVie's failure to describe the information that was produced in *King*, it is premature to place any limitations on what AbbVie should produce in this case.

B. ANDROGEL ADVERSE EVENT DATABASE

Document Request No. 39 seeks a complete copy of AbbVie's AndroGel adverse event database. In its Response, AbbVie asserted boilerplate objections and stated that it will produce certain data from its AEGIS database, "subject to clarification and a meet and confer regarding the scope" of this Request. AbbVie's RFP Response Nos. 39 (Ex. 3), at 26.

AbbVie refuses to produce adverse event information for any adverse event that does not involve an injury the type alleged in complaints filed in this litigation. As explained in detail herein, this position is contrary to law. Plaintiffs are entitled to conduct their own analysis of all adverse events that have occurred in patients taking AndroGel. Plaintiffs should be able to evaluate, for example, the manner in which each adverse event was classified, the relative frequency with which different types of adverse events were reported, and the timing of those reports. This information is indisputably relevant because it bears directly on when AbbVie had notice of, and the nature of, adverse events caused by its drug. This fundamental "***what they knew and when***" information is at the center of the failure-to-warn and negligence claims in this case. Additionally, adverse events are routinely allowed as a basis for admissible expert opinion regarding general causation. As such, there is no reasonable argument that the entire adverse event database should not produced without further delay.

AbbVie's position is that only adverse events of the same type as the injuries alleged in Plaintiffs' complaints, broadly defined as blood clotting and cardiovascular injuries, are relevant. To the contrary, any AndroGel adverse event information is relevant, and is also likely to lead to the discovery of admissible evidence concerning the risks associated with AndroGel, the efficacy of AndroGel, what AbbVie knew or should have known about AndroGel's risks and its efficacy, and to show how AbbVie responded when presented with such information. Accordingly,

adverse event information regardless of the type of injury is relevant to plaintiffs' negligence and failure to warn claims and to AbbVie's learned intermediary defense.

The PSC requests that AbbVie be required to produce a fully-functioning export from their Adverse Event database(s) containing all entries that relate to AndroGel and containing all fields (other than those that actually contain names or any information that would identify the patient or reporter), including all data or information within the Adverse Event database that is pulled from other linked data sources or databases. The export should be produced to the PSC in the form of a delimited text file that can be imported or loaded into a basic database software. The PSC also request that incremental updates to this production be made to the PSC, on a quarterly basis.[12]

(i) Adverse Event Databases, Data and Analysis are Discoverable for All Types of Reported Injuries

There is no legal basis for AbbVie to refuse to produce adverse event data for injuries that may not be directly alleged in Plaintiffs' complaints. Limiting the scope of discovery by type of injury will deprive Plaintiffs of important pharmacovigilance data, and would affect the accuracy and reliability of any data mining methodology applied to the adverse event database. Courts have specifically allowed evidence of adverse events different from a plaintiff's injury at trial as evidence of notice and as "signals" of adverse events.

> The adverse reaction reports constituted legally relevant evidence on the issue of notice to [manufacturer] of the potentially dangerous character of the shield.

[12] In the Pradaxa litigation, the parties agreed that the adverse event database at issue in that case, ARISg, would be updated twice a year. *See* March 14, 2013 Minute Order, *In Re Pradaxa (Dabigatran Etexilate) Products Liability Litigation*, Case No. 3:12-md-2385, (S.D. Ill.) (Ex. 17), at 2. This agreement followed the Court's direction that the parties meet and confer regarding the frequency with which the ARISg database production would be updated. *See In Re Pradaxa* Amended Case Management Order No. 17, dated January 2, 2013 (Ex. 18), at ¶ 5(b), p. 2.

> [Manufacturer's] knowledge of reported adverse consequences from the use of the shield was a significant component of [plaintiff's] claim that, by failing to eliminate these dangers or to give warning of them, [manufacturer] prevented her and her physician from making an informed decision on the use of the shield as a contraceptive device. The adverse reaction reports rendered the existence of notice of a dangerous or defective product more probable with the evidence than without it.
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> Although the adverse reaction reports included references to untoward consequences other than septic abortions, the nature of these other reported incidents did not impair the legal relevancy of the evidence. These other incidents were probative of notice to [manufacturer] that something might well be amiss with its product.
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> *Palmer v. A.H. Robins Co.*, 684 P.2d 187, 198-199 (Colo. 1984) (internal citations omitted).

Of course, if evidence is admissible, it is certainly discoverable. However, it cannot be overlooked that admissibility is not the test for the scope of allowed discovery. The scope of discovery is much broader. Even if some of the adverse event data may, ultimately, not be admitted as evidence at trial, AbbVie must nonetheless produce it. Courts have distinguished the issue of ultimate admissibility from the obligation to produce evidence relevant to the issue of notice and adequacy of warnings. *See, e.g., Hardy v. Pharmacia Corp.*, 2011 U.S. Dist. LEXIS 57119, *6-9 (M.D. Ga. May 27, 2011).

In the Yaz/Yasmin birth control litigation, the drug manufacturer was required to produce all adverse event data, regardless of the type of injury. Case Management Order No. 22 (Production and Inspection of the Clintrace Database and Data), *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Relevant Products Liability Litigation*, Case No. 3:09-md-2100 (S.D. Ill. Sept. 14, 2010) (Ex. 19). Because the manufacturer's licensing agreement for the adverse event database software prohibited it from producing an exact copy of the database, the Order required the defendant to both make a fully-functioning and complete copy of the database available for inspection by Plaintiffs and their experts pursuant to Fed. R.

Civ. P. 34, and also to produce a complete set of all data exported from the database in a Microsoft Excel table. *Id.* at 1-2. This Order recognizes two critical points. First, it is essential, as argued above, that plaintiffs be able to access, review and analyze all adverse events related to a drug, regardless of the type of event. Second, by permitting the Yaz Plaintiffs to access the full database with all of the functionality available to defendants, the Order ensures that the Plaintiffs can conduct a comprehensive analysis of ***all*** of the data that is available to the manufacturer, thus avoiding any cherry-picking or loss of functionality that would result from production of anything short of the complete adverse event database in the form that it is available to the manufacturer.

Furthermore, while AbbVie may argue that there is no relevance to adverse event reports regarding injuries that do not relate to the injuries at issue in this case, the PSC and its experts can only properly evaluate the rates of certain types of adverse events if they have both the numerator (the number of adverse events of a given type) and the denominator (the total number of adverse events). To use an oversimplified example, if ten blood clotting injuries were reported during a given year, it makes a big difference whether those were ten of 100 or ten out of 10,000 events.

It is not simply the number of adverse events that is relevant, however. As part of its evaluation of all AndroGel adverse events, the PSC has a right to review the injury type for each event and evaluate whether each adverse event was properly categorized. The PSC should not have to rely on the drug manufacturer's assessment and categorization of adverse events. Adverse events can be misclassified through inadvertence (such as by a reviewer who mistakenly checks the wrong box on a reporting form), as the result of a systemic flaw in the evaluation process, or to intentionally reduce the numbers of an event that can be categorized by various

possible terms. Regardless of how they occur, flawed assessments make their way into the database and affect the integrity of the data and any conclusions drawn from it.

Adverse event reports were of vital importance in *In re Pradaxa (Dabigatran Etexilate) Products Liability Litigation*, MDL No. 2385, Case No. 3:12-md-2385 (S.D. Ill.), where, as a result of discovery taken in the product liability lawsuit, it was determined that certain adverse events in the drug's pivotal clinical trial had been miscategorized. The manufacturer conducted an audit of the adverse events to reclassify them after lawyers representing plaintiffs determined that seven fatal adverse events may have been miscategorized. During their audit, the manufacture determined that 22 adverse events had, in fact, been miscategorized. These errors meant that the percentages of adverse events reported in the clinical trial were incorrect. The study results had been published in the New England Journal of Medicine, which also published the manufacturer's correction based on this audit. *See* Connelly, S., *et al., Additional Events in RE-LY Trial*, NEW ENGLAND JOURNAL OF MEDICINE, September 24, 2014 (Ex. 20). *See also* Schroll, J.B., *et al., Challenges in Coding Adverse Events in Clinical Trials: A Systematic Review*, PLOS ONE, April 13, 2012, (Ex. 21) (concluding that "there is a lack of evidence that coding of adverse events is a reliable, unbiased and reproducible process").

It is critical that the PSC and its expert scientists have the opportunity to review and evaluate the entire body of adverse events. A process, like the one AbbVie has proposed, by which AbbVie somehow gets to chose which events the PSC gets to review is inherently flawed. AbbVie does not have legitimate grounds for objecting to the production of its entire adverse event database.

(ii) Adverse Event Reports are Relevant and Admissible Evidence of Notice.

Adverse event reports are relevant and admissible evidence of AbbVie's knowledge of adverse events and the corresponding adequacy of its warnings. Courts consistently admit

AERs as evidence at trial in pharmaceutical product liability cases because "… "they constitute notice evidence." *In re Levaquin Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 163777, at *29-31 (J.P.M.L. Nov. 21, 2014); *see also Schedin v. Johnson & Johnson (In re Levaquin Prods. Liab. Litig.)*, 2010 U.S. Dist. LEXIS 145282, at *11 (D. Minn. Nov. 9, 2010). As explained in an order issued in this District denying defendant's motion to exclude evidence of adverse event reports from trial, "… "receipt of the reports is relevant on the issue of defendant's knowledge of adverse reactions." *Martinkovic v. Bangash*, 1987 U.S. Dist. LEXIS 11914, at *4-5 (N.D. Ill. Dec. 15, 1987). Notice of risks before the sale and use of the defective drug by plaintiffs is particularly important. As another court has explained, "adverse reaction reports known to [defendant] prior to the time of [plaintiff's] injury … [are] *highly relevant* to whether [defendant's] warnings were adequate prior to that date." *Sabel v. Mead Johnson & Co.*, 737 F. Supp. 135, 140-141 (D. Mass. 1990)(emphasis added.). There is no reasonable argument to the contrary, and there is no applicable authority for limiting the scope of discoverable adverse event data by time or type of reported adverse event.

(iii) Adverse Event Reports are Relevant and an Admissible Basis for Expert Analysis, Reports and Testimony Regarding Causation.

Adverse event reports are relevant and an admissible basis for expert analysis, reports and testimony regarding causation. Adverse event reports "are commonly used by experts in the field to determine causation in correlation with other evidence." *In re Levaquin Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 163777, at *29-31 (J.P.M.L. Nov. 21, 2014); *see also Schedin v. Johnson & Johnson (In re Levaquin Prods. Liab. Litig.)*, 2010 U.S. Dist. LEXIS 145282, at *11 (D. Minn. Nov. 9, 2010), *citing In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 961-62 (D. Minn. 2009) (allowing evidence of adverse event reports as a safety signal as discussed by Dr. Blume).

It is critical that AbbVie produce the entire adverse event database, not just those reports of blood clotting and cardiovascular events. When viewed in the context of the entire body of adverse events, adverse event reports are "signals" of an association between the drug and the injury at issue and "may be considered along with other evidence to determine whether the drug is a substantial contributing factor to the injury. These reports may be considered as one type of evidence of a signal that there may be an association between a drug and the adverse event." *In re Levaquin Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 163777, at *29-31 n.20 (J.P.M.L. Nov. 21, 2014). Data mining adverse event databases for "signals" and comparing them to those for other drugs is an industry standard. Such methodology satisfies the *Daubert* admissibility standards. *Glynn v. Merck Sharp & Dohme Corp. (In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.)*, 2013 U.S. Dist. LEXIS 51552, at *24-25 (D.N.J. Apr. 10, 2013).

Plaintiffs are entitled to access the databases necessary for their experts to conduct an independent analysis of the entire epidemiological profile of AndroGel in preparation for trial. Arbitrarily limiting the scope of the available data by injury type or otherwise will conceal potentially highly relevant and revealing data.

C. ABUSE OF RULE 33(d)

AbbVie has repeatedly attempted to invoke Federal Rule of Civil Procedure 33(d) when responding to the PSC's Interrogatories, but AbbVie failed to identify documents that contain responsive information with the specificity required by the Rule.

Rule 33(d) states as follows:

> If the answer to an interrogatory may be determined by examining, auditing, compiling, abstracting, or summarizing a party's business records (including electronically stored information), and if the burden of deriving or ascertaining the answer will be substantially the same for either party, the responding party may answer by:

> (1) specifying the records that must be reviewed, in sufficient detail to enable the interrogating party to locate and identify them as readily as the responding party could; and
> (2) giving the interrogating party a reasonable opportunity to examine and audit the records and to make copies, compilations, abstracts, or summaries.

Fed. R. Civ. P. 33(d).

AbbVie's responses to 64 of the PSC's 100 Interrogatories by invoking Rule 33(d). The majority of these responses state that "pursuant to Rule 33(d), information responsive to this Interrogatory will be produced." The pervasiveness of these "Rule 33(d) responses," combined with the staggeringly small volume of documents that have been produced to date, constitutes an egregious abuse of the discovery process. The PSC respectfully requests that the Court issue an Order compelling complete and proper responses to these Interrogatories. An Order making clear that this conduct will not be tolerated may go a long way toward preventing this type of abuse in the future.

Inexplicably, in response to some corresponding document requests, AbbVie objected to producing relevant documents at all. For example, AbbVie's Responses to Interrogatory No. 96(i), seeking information regarding the pricing of AndroGel, states that information can be found in "documents to be produced." However, the Responses to Request for Production No. 73, which requesting documents that reflect the pricing of AndroGel, indicates that AbbVie refuses to produce these documents. AbbVie must either produce and identify (by Bates stamp number)[13] the responsive documents in compliance with Rule 33(d), or provide answers to the Interrogatories.[14]

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[13] Courts require that documents be "clearly identified," and some have specifically required identification of pertinent documents by Bates number. *See, e.g, Remy Inc. v. Tecnomatic, S.P.A.*, 2013 U.S. Dist. LEXIS 45086, at *9-10 (S.D. Ind. Mar. 28, 2013). The PSC submits that for the majority if not all of the documents to be identified here, providing Bates numbers would be the most concise and

Rule 33(d) is not automatically available to a responding party as a matter or preference or convenience. "A party responding to an interrogatory may not take advantage of Rule 33(d) unless it can show that 'the burden of deriving or ascertaining the answer is substantially the same for the party serving the interrogatory as for the party served.'" *In re Sulfuric Acid Antitrust Litig*., 231 F.R.D. 351, 366 (N.D. Ill. 2005). Further, even if invoking Rule 33(d) is appropriate based on the burden requirement, generally pointing to, or offering to produce, thousands or millions of pages of documents is not an acceptable response. As explained by the advisory committee regarding Rule 33(d):

> … parties upon whom interrogatories are served have occasionally responded by directing the interrogating party to a mass of business records or by offering to make all of the records available, justifying the response by the option provided by this subdivision. ***Such practices are an abuse of the option***.
>
> Fed. R. Civ. P. Advisory Committee's note, 1980 Amendment to subdivision (c) (renumbered subdivision (d) by 1993 Amendments) (emphasis added).

Similarly, general references to prior discovery responses such as Initial Disclosures[15] do not satisfy the requirements of Rule 33(d) because such documents are not the responding party's

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unambiguous method for identifying the documents that contain the answers. But, the PSC acknowledges that better identification methods may exist under some circumstances.

[14] During a phone conversation on December 12, 2014, and in the interest of getting some of the critical information the PSC needs sooner than we would likely get it if forced to file a motion to compel, the PSC proposed that we would hold off on filing a motion if AbbVie would agree to provide substantive responses to a short list of interrogatories. We reiterated this proposal and identified a list of 17 interrogatories in the PSC's December 15, 2014 letter. *See* Ex. 7 at 5. In response, on December 22, AbbVie stated that it was considering the proposal. *See* Ex. 8 at 3-4. It its December 30 letter, AbbVie was more specific in stating that it would consider the proposal in the early part of 2015. *See* Ex. 11 a 1-2. On January 12, 2015, AbbVie's counsel stated that they had no authority to answer any of the 17 Interrogatories. *See* Katz Decl. (Ex. 5) at ¶ 8.

[15] AbbVie's responses to Interrogatories 7, 8, 19, 44, 63, 66, 84, 85 and 93 refer Plaintiffs' to its Initial Disclosures. However, in most cases the Initial Disclosures do not contain the requested information. For example, Interrogatory No. 8 requests AbbVie to identify the names and present or last known addresses of key employees with knowledge pertaining to AndroGel. Responses to PSC's Interrogatories, Ex. 4, at 11-12. In response, AbbVie refers to its Initial Disclosures, which identify 23

business records. *Davis v. City of Springfield*, 2009 U.S. Dist. LEXIS 6737, at *14 (C.D. Ill. Jan. 30, 2009).

AbbVie has failed to satisfy the requirements of Rule 33(d). It responded to the Interrogatories at issue with various generic references to documents, including to the Initial Disclosures, "the IND and NDA for AndroGel," and unspecified "documents to be produced." *See, e.g.*, Response to PSC's Interrogatories Nos. 52 and 92, (Ex. 4, p. 53 and 81). Even if AbbVie can establish that invoking Rule 33(d) for all or some of these Interrogatories is appropriate based on the allocation of burden (which it has not), it must identify the specific documents and sources that it would have to be reviewed in order to compile the answers, and give Plaintiffs access to each such document and source for each such Interrogatory. Otherwise, AbbVie is required by the Rule to provide substantive answers to these Interrogatories.

Additionally, AbbVie seems to think that it will first identify and review potentially responsive information, then produce it (which would take place over many months) and only then supplement the Interrogatory responses to state which document contain the responsive information. This would mean that Plaintiffs would get answers to these Interrogatories many months and perhaps even years after this fundamental discovery was served. This is not what the Federal Rules contemplate and is obviously unworkable.

(i) The Interrogatories at Issue Seek Relevant and Discoverable Information

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potential custodians but do not state their present or last known addresses. *See* Initial Disclosures, Ex. 22, at 2-3. Additionally, this list of potential custodians in the Initial Disclosures does not, as Interrogatory No. 8 requests, specify the time period during which the identified individuals held their AndroGel-related positions. *See id.*

(a) Interrogatory Nos. 10, 20, 23-32, 38, and 81 (Clinical Trials, Studies and Medical Literature)

These interrogatories seek information regarding clinical trials, studies, and scientific publications related to AndroGel and TRT. This information is directly relevant to the issues in this litigation, including causation and notice, and AbbVie's learned intermediary defense. Interrogatories Nos. 10 and 81 ask AbbVie to identify every AndroGel trial or study, and to provide detailed information such as basic identifying information for each study, whether the study results were submitted to the FDA, and the dates of submission. Similarly, Interrogatories Nos. 20 and 23 - 31 request that AbbVie identify the studies that it relied on for determining the safety, efficacy, and other attributes of AndroGel. Interrogatory No. 32 requests that AbbVie identify medical literature in its possession that sets forth elevated risks of adverse reactions from use of AndroGel. Interrogatory No. 38 requests that AbbVie identify consultants or other non-employees who conducted studies or evaluations of AndroGel.

AbbVie asserted boiler plate objections to these requests and responded that "pursuant to Rule 33(d), responsive information to this Interrogatory will appear in the documents it will produce including but not limited to the IND and NDA submissions to the FDA for AndroGel." This response does not satisfy the requirements of Rule 33(d). The IND and NDA submissions are voluminous, encompassing hundreds of thousands of pages. A general reference to them, without more, is insufficient to enable Plaintiffs to locate the information they are seeking as readily as AbbVie can, as required by Rule 33(d). Further, AbbVie's response, which identifies documents "including but not limited to" the IND and NDA, indicates that there are other documents that contain responsive information which AbbVie does not even attempt to identify. AbbVie must either supplement these responses with the information required by Rule 33(d) or answer these interrogatories.

(b) Interrogatory Nos. 8, 19, 44 (Identity of Knowledgeable Employees/Agents)

These interrogatories seek information regarding the identities of the individuals involved in such fundamental functions as the development, regulatory approval, pharmacovigilance, marketing and sale of AndroGel. AbbVie responded to these requests, in part, by generally referencing its Initial Disclosures (Responses to Interrogatories No. 8, 19 and 44, Ex. 4 at p. 14, 24 and 47)). Such general references are insufficient. Furthermore, Initial Disclosures are not business records and references to Initial Disclosures are not a proper Rule 33(d) response. *See Davis v. City of Springfield*, 2009 U.S. Dist. LEXIS 6737, at *14 (C.D. Ill. Jan. 30, 2009).

These interrogatories are calculated to identify potential witnesses with knowledge of admissible evidence. For AbbVie to refuse to provide this most basic and fundamental information is an egregious failure to properly respond to discovery. Furthermore, as stated previously, identifying the company employees who may possess relevant information will allow the PSC to identify those whose custodial files we wish to have produced and may alleviate the need for AbbVie to produce files for those employees who have less central roles related to AndroGel, which will lighten AbbVie's burden. AbbVie must specify "the records that must be reviewed, in sufficient detail to enable the interrogating party to locate and identify them as readily as the responding party could." Fed. R. Civ. P. 33(d). Otherwise, they should simply answer the questions.

(c) Interrogatory Nos. 39- 42, 43, 68-74 (Adverse Events)

Interrogatories Nos. 39-42 seek information regarding reports of adverse events, complaints and concerns from healthcare professionals, consumers, and others, and any responsive actions to these, regardless of their nature (related or not to pro-thrombotic events). Interrogatories 43 and 68-74 seek information regarding complaint history, *e.g.* how many

adverse events were reported and when, and ask AbbVie to provide a "timeline of reported complaints" and a "comparison rate of complaints versus usage." This information is relevant to the Plaintiffs' negligence and failure to warn claims, and is routinely discoverable and admissible in pharmaceutical cases.

AbbVie responded with generic references to letters to healthcare providers, the AEGIS and AIRMS databases, the IND and NDA submitted to the FDA for AndroGel, or to other unspecified "documents to be produced." AbbVie must either answer the interrogatories as asked, or identify the specific documents that it would have to review in order to compile the answers and give Plaintiffs access to each such document. *See* Fed. R. Civ. P. 33(d).

(d) Interrogatory Nos. 11, 12, 13, 14, 18, 37, 64, 77 (Regulatory/Labeling)

Interrogatories Nos. 11 and 56 seek information regarding AbbVie's FDA submissions for AndroGel and related communications with the FDA. Interrogatories Nos. 12, 13, 14, 18, 37, 64, 76, 77 seek information regarding label and warning information for AndroGel, "Dear Doctor" letters, Consumer Medical Information, the AndroGel package insert, warnings and precautions for AndroGel. This information is directly relevant to Plaintiffs' negligence and failure to warn claims.

In response, AbbVie invoked Rule 33(d) without specifying the documents that Plaintiffs must review to locate the responsive information. AbbVie must either answer the interrogatories as asked, or identify the specific documents that it would have to review in order to compile the answers and give Plaintiffs access to each such document. *See* Fed. R. Civ. P. 33(d).

(e) Interrogatory No. 16 (Foreign Regulatory Information)

This interrogatory asks AbbVie to "[i]dentify any governmental agency in any country worldwide that declined to approve or challenged, or asked for additional study before approving" AndroGel.

Discovery of foreign regulatory information is routinely permitted in pharmaceutical litigation and is often deemed admissible at trial. *See e.g., In re Yasmin & Yaz (Drospirenone) Mktg.*, 2011 U.S. Dist. LEXIS 147935, at *70 (S.D. Ill. Dec. 22, 2011) (admitting evidence of foreign regulatory actions and labeling because this information bears on notice and knowledge available to the manufacturer and whether such information was properly utilized in the United States); *Hardy v. Pharmacia Corp.*, 2011 U.S. Dist. LEXIS 57119, *6-9 (M.D. Ga. May 27, 2011) ("Plaintiff could use the [foreign] labels and product guides to discover what Defendants knew about potential risks, what follow-up investigations Defendants did to learn more about those potential risks, and other facts that are potentially relevant to the risk-utility analysis. For these reasons, the Court finds that the labels and guides Plaintiff seeks are not outside the scope of permissible discovery."); *Schedin v. Johnson & Johnson (In re Levaquin Prods. Liab. Litig.)*, 2010 U.S. Dist. LEXIS 145282, at *11-13 (D. Minn. Nov. 9, 2010) (admitting evidence of foreign regulatory action to show notice and motive); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp.2d 531, 553 (S.D.N.Y. 2004) (finding "no legal basis" upon which to rule that "testimony regarding foreign regulatory actions is irrelevant as a matter of law in a United States products liability case governed by American law."); *Madden v. Wyeth*, 2006 WL 7284528, at *2 (N.D. Tex. Jan. 12, 2006) (ordering the production of foreign labeling documents and other related information because such information is "relevant to whether defendant intentionally diluted the warnings on the same products sold in the United States.").

AbbVie did not answer this interrogatory, instead referencing the IND, NDA and other "documents to be produced." This response does not comply with the requirements of Rule 33(d). AbbVie must either answer the interrogatory as asked, or identify the specific

documents that it would have to review in order to compile the answer and give Plaintiffs access to each such document. *See* Fed. R. Civ. P. 33(d).

(f) Interrogatory Nos. 46, 48, 49, 52, 84, 85, 86, 87, 96, 97, 100 (Sales/Marketing/Public Relations)

These interrogatories seek information regarding the marketing, advertising and promotion of AndroGel and the individuals responsible for these activities. This information is routinely discoverable in pharmaceutical cases. *See, e.g., Cunningham v. SmithKline Beecham*, 255 F.R.D. 474, 479-480 (N.D. Ind. 2009); *Forst v. Smithkline Beecham Corp*., 2008 U.S. Dist. LEXIS 96557, at *6-7 (E.D. Wis. Nov. 18, 2008); *Henson v. Wyeth Laboratories, Inc*., 118 F.R.D. 584, 585-586 (W.D. Va. 1987); *Gentile v. Biogen Idec, Inc.*, 2014 Mass. Super. LEXIS 16, at *2-3 (Mass. Super. Ct. 2014).

AbbVie responded to these with an insufficient general reference to "the documents it will produce" pursuant to Rule 33(d). AbbVie must either answer the interrogatories as asked, or identify the specific documents and sources that it would have to review in order to compile the answers and give Plaintiffs access to each such document and source. *See* Fed. R. Civ. P. 33(d).

(g) Interrogatory No. 92 (Outside Consultants)

This interrogatory seeks the identities of outside consultants paid by Defendants for services related to AndroGel. This request is calculated to seek out potential witnesses and sources of admissible information.

AbbVie responded with an insufficient general reference pursuant to Rule 33(d) to "the documents to be produced." AbbVie must either answer the interrogatories as asked, or identify the specific documents that it would have to review in order to compile the answers and give Plaintiffs access to each such document. *See* Fed. R. Civ. P. 33(d).

(h) Interrogatory No. 6 (Development and Design)

This interrogatory seeks information regarding changes in the design of AndroGel. It seeks information relevant to Plaintiffs' design, negligence, and failure to warn claims.

AbbVie's response generally refers to the AndroGel IND and NDA and other, unspecified documents that it will produce. AbbVie must either answer the interrogatory as asked, or identify the specific documents that it would have to review in order to compile the answer and give Plaintiffs access to each such document. *See* Fed. R. Civ. P. 33(d).

(i) Interrogatory No. 7 (Litigation/Liability insurance)

This interrogatory seeks information regarding insurance and indemnity agreements that may cover any damages in this litigation.

AbbVie's response improperly refers Plaintiffs to its Initial Disclosures, which are not business records and references to Initial Disclosures are not a proper Rule 33(d) response. *See Davis*, 2009 U.S. Dist. LEXIS 6737, at *14. AbbVie must either answer the interrogatory, or identify the specific documents that it would have to review in order to compile the answers and give Plaintiffs access to each such document. *See* Fed. R. Civ. P. 33(d).

V. CONCLUSION

Based on the foregoing, the PSC respectfully requests that the Court enter an order compelling AbbVie to provide the documents and information set forth above within 15 days of the Court's Order.

DATED: January 16, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 16, 2015, the foregoing Memorandum of Law in Support of the PSC's Motion to Compel Discovery From Defendants AbbVie Inc. and Abbott Laboratories was electronically filed with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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