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UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE)	Case No. 14 C 1748
REPLACEMENT THERAPY)	
PRODUCTS LIABILITY LITIGATION)	MDL No. 2545
)	
This document relates to all cases)	Judge Matthew F. Kennelly

ABBVIE'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL

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Plaintiffs' Motion to Compel, apparently the first in a "series" of threatened discovery motions, is without factual or legal basis and should be denied. Counsel for AbbVie has attempted in good faith to resolve every dispute issued in Plaintiffs' Motion without success. Granting Plaintiffs' initial Motion will remove any incentive for the parties to resolve discovery disputes without judicial intervention, increase the likelihood of discovery disputes in the future, and potentially distract the Court and the parties from their core MDL objectives, including preparing cases for trial. Plaintiffs seek to compel additional discovery from AbbVie on three topics.

First, Plaintiffs demand that AbbVie re-produce every document and deposition transcript in the *King v. Solvay* case. Abbott (AbbVie's predecessor regarding AndroGel in the U.S.) acquired Solvay in 2010 and the *King* case is a *qui tam* matter arising from healthcare reimbursement issues for two Solvay products in addition to AndroGel. The two cases do not share a single cause of action, and the claims and allegations in that case and this MDL are largely different. Nevertheless, AbbVie proposed to review and produce relevant documents produced by the Defendants in *King* in a reasonable time frame. Plaintiffs rejected this reasonable compromise.

Second, Plaintiffs move for a wholesale production of all AndroGel adverse event data from AbbVie's adverse event database (AEGIS), along with secondary, supporting documentation. Much of this data has nothing to do with injuries alleged in this MDL, which are limited to strokes, heart attacks, and blood clots. Adverse event data regarding "flatulence," "ankle fracture," "animal bite," and "job dissatisfaction" is wholly irrelevant to Plaintiffs' claims. Moreover, MDL and other federal courts have routinely rejected efforts to require pharmaceutical companies to produce underlying supporting adverse event data. AbbVie's multiple offers to resolve this issue by producing substantial additional data have all been rejected.

Finally, Plaintiffs attack AbbVie's interrogatory responses, including its references to produced documents that are expressly authorized by Fed. R. Civ. P. 33(d). In reality, the

Plaintiffs—not AbbVie—are operating well outside of the federal rules governing discovery. Counting subparts, as Rule 33(a) expressly requires, Plaintiffs have served 522 interrogatories. AbbVie has done its best to respond to this overbroad written discovery in a reasonable fashion and been rewarded with the present Motion to Compel.

For the reasons set out below, the Court should reject Plaintiffs' unreasonable discovery demands. Instead, AbbVie respectfully urges this Court to enter an order that tracks the provisions set out in the Conclusion below.

BACKGROUND

Plaintiffs' Motion is largely constructed on two premises—that AbbVie is delaying discovery and that AbbVie refuses to resolve disagreements over discovery. The record in this matter demonstrates that both of these premises are flatly wrong.

Discovery in this MDL effectively commenced on August 15, 2014, when Plaintiffs issued courtesy copies of their discovery requests to AbbVie, including *187* requests for the production of documents and *522* interrogatories, including discrete subparts. The negotiated response date to such discovery was November 14, 2014 and CMO 13 provided for rolling document productions that same day.

Since November 14, AbbVie has produced over 2 million pages of documents in accordance with CMO 13. That production includes the AndroGel IND/NDA files (roughly 500,000 pages), five custodial files (consisting of approximately 1.4 million pages resulting from use of search terms from the Illinois state court litigation since Plaintiffs in this MDL have delayed agreement to a list of proposed search terms), organizational charts, document retention and computer use files, and other materials. AbbVie is currently working on producing 18 additional custodial files, has produced two witnesses for Rule 30(b)(6) depositions, and responded to Plaintiffs' interrogatories. This level of discovery activity evidences no delay on the part of AbbVie.

Moreover, AbbVie has consistently attempted to resolve any discovery disputes with Plaintiffs, including the discrete issues covered by the Motion to Compel. In many instances, counsel for AbbVie has made multiple or serial proposals to resolve these discovery issues. These efforts have largely been ignored or rejected. Accordingly, the fact that the Court is now required to rule on the present Motion is in no way a result of AbbVie's reasonable discovery positions.

LEGAL STANDARD

"[D]iscovery is not to be used as a fishing expedition." *EEOC v. Walner & Assoc.*, 91 F.3d 963, 971-72 (7th Cir. 1996). The Federal Rules do not allow "unlimited discovery"; instead they give judges "broad discretion to tailor discovery narrowly and dictate its sequence." *Awalt v. Marketti*, 2012 WL 6568242, at *3 (N.D. Ill.). This "court has the ability to limit discovery if it determines that: (1) the discovery sought is unreasonably cumulative; (2) the party seeking discovery has had ample opportunity to obtain the information sought; or (3) the expense or burden of the proposed discovery outweighs its likely benefit." *Am. Hardware Mfrs. Ass'n v. Reed Elsevier*, 2007 WL 4224340, at *2 (N.D. Ill.) (citing Fed. R. Civ. P. 26(b)(2)). Such limitations are particularly appropriate where the party seeking discovery has not shown that its denial will result in "actual and substantial prejudice" to its interests. *WH Holdings v. Ace American Ins.*, 2010 WL 3732149, at *3 (N.D. Ill.) (quoting *Sears v. Glasser*, 64 F.3d 1061, 1068 (7th Cir. 1995)). That is the case here with the present Motion.

ARGUMENT

Although Plaintiffs claim to be seeking discovery "so indisputably relevant that we should not have to take up the Court's time with this motion" (Mem. at 6.), the factual record makes abundantly clear that this position is without foundation.

I. This Court should deny Plaintiffs' request for all *King v. Solvay* documents and deposition transcripts.

Plaintiffs seek *all* documents and deposition transcripts from *King v. Solvay* regardless of relevance or sources within 15 days. (Mem. at 1, 7.) This request should be denied. AbbVie is willing to (1) review and produce, within a reasonable time, documents produced by the Defendants in that matter that are relevant to this MDL; and (2) meet and confer with Plaintiffs following that production regarding further discovery from the Solvay era.

A. Plaintiffs' request for all *King* discovery is overly broad, because *King* is a different type of case with different drugs and different issues.

Solvay Pharmaceuticals sold AndroGel in the U.S. from 2000 to 2010. Abbott acquired Solvay in 2010, and in 2013 Abbott spun off its research-based pharmaceutical business including AndroGel (in the U.S.) into a separate company, AbbVie.

King is a qui tam lawsuit—not a product liability case—brought in the Southern District of Texas in 2003, when Solvay still owned AndroGel, long before Abbott's 2010 purchase and years before most of the MDL Plaintiffs began using AndroGel. The King case focuses solely on Solvay's conduct before 2008. The complaint alleges that various state and federal healthcare programs paid out claims as a result of unapproved promotion of three Solvay prescription medications. (King Fifth Am. Compl. ¶¶ 2-3.) AndroGel is one of those three. (Id.) The other two products are irrelevant to this MDL: Luvox treats obsessive compulsive disorder, and Aceon treats essential hypertension and stable coronary artery disease. (Id. ¶¶ 66, 126.) Neither of these products are testosterone drugs. And while this MDL is focused on alleged personal injuries caused by AndroGel, King involved no allegations of personal injuries.

Plaintiffs attach to their Memorandum (Ex. 15) portions of the document requests in *King*, which may create the erroneous impression that these two matters are identical. That is incorrect. The full document requests from *King* include 72 requests about Luvox and 91 requests about Aceon, resulting in a total of 163 requests that have nothing to do with AndroGel. (*King* ECF 188-3 at 8-27.) AbbVie estimates that roughly two-thirds of the documents produced in *King* concerned Luvox and Aceon not AndroGel.

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With respect to AndroGel, there is some overlap regarding the marketing allegations but the two cases are vastly different. (Mem. at 11 (admitting the cases are not "coextensive").) They do not share a single cause of action and many allegations in *King* have absolutely nothing to do with claims in this MDL. For example:

- Women. *King* alleges that women use AndroGel (*King* Fifth Am. Compl. ¶¶ 210-14), but every AndroGel user in this MDL is a man.
- <u>Diabetes</u>. *King* alleges that AndroGel has been used to treat diabetes (*id*. ¶¶ 215-16), but no MDL plaintiff alleges this use.
- <u>HIV/AIDS</u>. *King* alleges that AndroGel has been used to treat HIV/AIDS wasting (*id.* ¶¶ 177, 219-21), but no MDL plaintiff alleges this use.
- Opiates. *King* alleges that AndroGel has been used to treat testosterone loss caused by the long-term use of opiates (*id.* ¶ 218), but no MDL plaintiff alleges this use.
- <u>Pain killers</u>. *King* alleges that AndroGel has been used as a substitute for pain killers (*id*.), but no MDL plaintiff alleges this use.
- Government healthcare reimbursement. *King* alleges that state and federal healthcare reimbursement programs inappropriately paid for AndroGel prescriptions (*id.* ¶¶ 1-3, 366-68, 373-74), but no MDL plaintiff asserts such a claim.

In sum, *King* addresses AndroGel in the broad context of healthcare reimbursements involving three drugs and this MDL focuses on AndroGel alone in the narrow context of specific personal injuries—strokes, heart attacks, and blood clots. There is some overlap in the AndroGel marketing allegations between the two cases, but most documents produced in *King* are irrelevant to this MDL.

B. AbbVie must be granted reasonable time to review the *King* documents for relevance and responsiveness to this MDL.

This Court should reject Plaintiffs' demand that AbbVie produce *all* the documents from *King* in 15 days. Plaintiffs have not established that these documents are relevant and the limited overlap in the AndroGel marketing allegations does not justify their immediate wholesale production.

The fact that there may be some overlap between the cases is "not enough to require a carte blanche production of all documents" from another case. *Chen v. Ampco Sys. Parking*,

2009 WL 2496729, at *2 (S.D. Cal.); see also King Cnty. v. Merrill Lynch, 2011 WL 3438491, at *2–3 (W.D. Wash.) (denying a request for failure to make the required showing of relevance); Capital Ventures v. J.P. Morgan, 2014 WL 1431124, at *2 (D. Mass) (denying production of "all documents produced in other actions" unless the documents were responsive to case-specific search terms); Lima v. PHL Variable, 2014 WL 5471760, at *1 (D. Conn.) ("Similar allegations and/or potential witnesses are not a basis for production of all documents produced in other cases").

AbbVie is willing to produce some of the documents that the Defendants produced in *King*, after (a) removing documents that relate solely to the other drugs, (b) removing documents that relate to AndroGel but are irrelevant to this MDL; and (c) redacting information about other drugs that appears in relevant AndroGel documents. Plaintiffs already *agreed* to such redactions: the protective order entered by this Court states, "Defendants also may redact information regarding their other products unrelated to products at issue in the Testosterone Litigation." (CMO 9.) Given this negotiated redaction protocol, a production demand for non-testosterone drugs is facially unreasonable.

Reviewing the *King* documents for relevance and responsiveness will take far longer than the 15 days Plaintiffs would give AbbVie. The *King* document production, which covers 1999 through 2008, was expansive and expensive: it includes hard copy documents selected from thousands upon thousands of boxes stored in a warehouse, as well the restoration of backup tapes used to restore legacy Solvay electronic data. The defendants produced approximately *1.3 million pages* of documents, of which AbbVie estimates that roughly less than one-third relate in

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¹ To justify this unreasonable timing, Plaintiffs claim they have been requesting *King* documents since April 2014, prior to the creation of this MDL, when one of their lawyers sent AbbVie an informal letter asking why the *King* documents had not already been produced. (Mem. at 1, 7 & Exs. 12-13.) The first discovery request for Solvay documents only arrived on August 15, when this Court lifted the MDL discovery stay. CMO 13, which was drafted by Plaintiffs' counsel, does not require production of *King* documents at any specific time. Nor could the *King* production be produced here any sooner, because the production in *King* itself only finished at the end of 2014.

some way to AndroGel. This represents a huge review population, particularly given the large volume of non-*King* documents already being reviewed for production in this MDL. AbbVie's attorneys in the MDL need a reasonable amount of time to coordinate with the *King* attorneys, review the AndroGel-related documents from *King* for relevance and responsiveness in this MDL, and redact from the relevant and responsive AndroGel documents any discussion of other drugs. AbbVie proposes to complete this substantial amount of work via rolling productions over a minimum of 120 days.²

C. Plaintiffs' request for deposition transcripts should be deferred.

AbbVie asks that any decision on identifying and producing deposition transcripts from *King* be deferred until after the parties finish negotiating and the Court enters the deposition protocol. The current draft deposition protocol specifically addresses whether and how prior testimony of a deponent must be produced, but the issue has not yet been resolved. (ECF No. 538 (discussing deposition protocol).)

Some of the *King* depositions do not discuss AndroGel, and others mention AndroGel and other Solvay drugs. AbbVie needs a reasonable amount of time to review those transcripts for relevance and responsiveness and to redact from any relevant and responsive transcripts discussions of other drugs. *See also Capital Ventures*, 2014 WL 1431124, at *1 (denying "wholesale production of all testimonial materials from all employees in all cases or investigations that have any relation at all to" claims in the present case).

D. Discussion about any other discovery from the Solvay era should be deferred.

As explained above, the discovery in *King* was expansive and expensive, including documents from thousands of boxes stored in warehouses and from legacy electronic systems that were restored from backup tapes (which Plaintiffs in *King* split the costs for). In short,

² During recent meet-and-confer discussions, AbbVie offered to start this production on February 23, to be completed within 120 days thereafter. Plaintiffs objected, and even attempted to add new terms not previously discussed by the parties. AbbVie expects the parties to continue to work on an agreement.

extraordinary measures were taken in *King* to locate archival material about AndroGel and the other drugs.

AbbVie has explained to the MDL Plaintiffs that they will be the beneficiaries of these extraordinary measures, and that *King* discovery ought to satisfy any obligation that AbbVie has to produce archived documents from the era before Abbott acquired Solvay. AbbVie would still, of course, produce relevant Solvay-related material that is reasonably accessible and within the search parameters established in this case. Examples include Solvay regulatory and adverse event information that was transferred to databases that AbbVie now uses and email files of former Solvay employees who now work at AbbVie. But given the large volume of Solvay-era materials that AbbVie will be producing already, AbbVie does not believe that it should be once again required to take on the extraordinary burden of reopening old warehouses and attempting to restore unused electronic tapes.

This is an extremely important issue. As Plaintiffs know from the Rule 30(b)(6) deposition that they took of AbbVie's corporate e-discovery designee, there are thousands of backup tapes with Solvay data that have never been indexed or inventoried in any meaningful way. Courts generally agree that backup tapes are "presumptively inaccessible." Kleen Products v. Packaging Corp. of Am., 2012 WL 4498465, at *18 (N.D. Ill.) (emphasis added). In some instances, as was done in King, costs are allocated to the party seeking the restoration of backup tapes. Clean Harbors v. ESIS, 2011 WL 1897213, at *2 (N.D. Ill.) (granting cost-shifting: "when information is stored on backup tapes, it is likened to paper records locked inside a sophisticated safe to which no one has the key or combination."); Major Tours v. Colorel, 2009 WL 3446761, at *6 (D.N.J.) (granting cost-splitting). AbbVie has reserved its rights regarding any restoration from backup tapes, including limiting the scope to ensure that it is not duplicative of other discovery, as well as cost allocation for any restoration.

II. This Court should deny Plaintiffs' request for a wholesale production of AbbVie's AndroGel adverse event database and supporting documentation.

There is no dispute about whether AbbVie will produce information from the AndroGel adverse event database. AbbVie has repeatedly made clear its willingness to do so. Rather, the current argument relates to the scope of that production. Plaintiffs demand production of AbbVie's *entire* adverse event database for AndroGel, including database entries that are *not* in any way related or relevant to the injuries Plaintiffs allege in their Complaints. (Mem. at 12, 13 ("all entries that relate to AndroGel and containing all fields...including all data or information ... pulled from other linked data sources or databases"). As discussed below, Plaintiffs' request would also impose a heavy and unnecessary burden to redact patient information from the underlying records of adverse events to produce irrelevant data. For both reasons, this Court should deny Plaintiffs' request.

A. Plaintiffs' request for irrelevant adverse event reports is overly broad and unduly burdensome.

AbbVie's adverse events database contains entries for all adverse events reported to AbbVie, at any time, from sources such as users, doctors, and hospitals around the world. Pursuant to federal regulations, this data includes "any adverse event associated with the use of a drug in humans, whether or not considered drug related..." 21 C.F.R. § 314.80 (emphasis added).

AbbVie's database thus includes entries that have no relevance whatsoever to this MDL which is focused on stroke, heart attack, and blood clots. For example, there are database entries for AndroGel about:

• <u>Irrelevant medical or body issues.</u> Examples include "flatulence," "change of bowel habit," "ankle fracture," "West Nile viral infection," "breath odour," "dry mouth," "lip dry," and others.

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³ Plaintiffs' brief also requests incremental updates on a quarterly basis. (Mem. at 13.) This is the first time plaintiffs have ever made this request. It has not been the subject of any meet and confer between the parties. AbbVie objects to the requested frequency of these updates as burdensome and disruptive to the operation of its business, and AbbVie suggests that the parties confer about the issue.

- <u>Product and package problems</u>. Examples include "device malfunction," "product closure removal difficult," "product container issue," "product packaging quantity issue," "product size issue," "suspected counterfeit product" and others.
- <u>Skin irritation.</u> Examples include "acne," "rash," "application site reaction," "dry skin," "cold feeling," "scratch," and others.
- <u>Improper use</u>. Examples include "drug administered at inappropriate site," "drug administration error," "intentional overdose," "intentional underdose," and others.
- Other random issues. Examples include "animal bite," "job dissatisfaction," "food poisoning," "hunger," "economic problem," and others.

These database entries are irrelevant to the strokes, heart attacks, and blood clots alleged in this case, including entries that are not even medical in nature. Thus, not everything in the database is plainly relevant or subject to legitimate discovery.

Courts in product liability cases typically permit discovery only into adverse event data that relate to the injuries alleged in the litigation. *See, e.g., Avendt v. Covidien*, 2013 WL 3941367, at *2 (E.D. Mich.) (plaintiff's request for all adverse event reports was overly broad in time and scope and unduly burdensome); *Autery v. SmithKline Beecham*, 2010 WL 1489968, at *2 (W.D. La.) ("Clearly, had plaintiff sought all adverse or spontaneous adverse reports, that request would be overly broad and unduly burdensome."); *Conklin v. Invacare*, 2007 WL 2492728, at *2 (W.D. Pa.) (denying motion to compel adverse event reports about problems different than those alleged in the litigation); *Davidson v. Ortho-McNeil Pharm.*, 2006 WL 1037072, at *1 (M.D. Fla.) (allowing discovery of adverse event reports that were related to injuries at issue in the case). Nonetheless, in the spirit of compromise, AbbVie has agreed to produce some portions of the adverse event database, even for obviously irrelevant adverse events.⁴

⁴ *None* of the authorities Plaintiffs cite support the production of adverse event data unrelated to the injuries alleged in this MDL. Instead, the cited cases stand for the unremarkable proposition that some adverse events are discoverable, depending on the circumstances of the case. For example, in *Palmer v. A.H. Robins*, 684 P.2d 187, 197 (Colo. 1984), the plaintiff sued the manufacturer of an intrauterine device, alleging that she became pregnant while using the device and subsequently suffered a spontaneous septic abortion, went into septic shock, and developed a blood disorder which required her to undergo a total hysterectomy. The court described the event reports at issue as involving "various problems associated with the use of the shield, including

Plaintiffs argue that they need the entire adverse event database, including lower-level data, to analyze causation. This position is plainly wrong. Source material for adverse events is notoriously unreliable for proving causation because it includes literally everything ever reported about a drug. The FDA recognizes that the adverse event data, which is freely available via the online database FDA Adverse Event Reporting System ("FAERS"), "have limitations ... [T]here is no certainty that the reported event (adverse event or medication error) was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event ... Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population" (emphasis added).⁵

Like the FDA, courts recognize that adverse event data is collected "without any medical controls or scientific assessment," and as a result are "one of the least reliable sources to justify opinions about both general and individual causation." *McClain v. Metabolife*, 401 F.3d 1233, 1250 (11th Cir. 2005); *see also In re Baycol Prod. Litig.*, 532 F. Supp. 2d 1029, 1051-52 (D. Minn. 2007) ("[Adverse event report] data and analyses have not been a generally accepted method by which to compare drugs."); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) ("case reports are not reliable scientific evidence of causation, because they simply described reported phenomena without comparison to the rate at which the phenomena

such conditions as septic abortions, unplanned pregnancies, uterine perforations, and infections." *Id.* at 198. These related directly to the claims in the litigation. The *Palmer* court never suggested that unlimited discovery for all adverse events is permissible, particularly if unrelated to the case. Plaintiffs also rely on an order from the *In re Yasmin and Yaz* litigation but that order was apparently entered under different circumstances and Bayer did not object to the production. That said, the scope of the production was limited, as the Court noted that the drug manufacturer was "not required to provide as part of this inspection(s) any other documents or materials relating to an adverse event report, including but not limited to patient medical records, which have been requested by Plaintiffs and shall be the subject of further discussions among the parties." *In re Yasmin & Yaz*, No. 09-md-2100, slip op. at 1-2 (S.D. Ill.) (attached hereto as Ex. 6).

⁵ FDA Adverse Event Reporting System (FAERS), http://www.fda.gov/Drugs/Guidance ComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation."). Adverse event reports will not help Plaintiffs establish general causation, much less specific causation.

The cases Plaintiffs cite do not suggest a different result. Schedin v. Johnson & Johnson (In re Levaquin Prods. Liab. Litig.), 2010 U.S. Dist. LEXIS 145282 (D. Minn.), did not examine the scope of discovery. Instead, the order resolved defendants' motion in limine relating to "evidence of tendon-related adverse events ... from ... the [adverse events database] database maintained by Defendants." Schedin v. Johnson & Johnson et al., No. 08-cv-5743, Dkt. 76 (attached hereto as Ex. 1) (emphasis added). The Schedin court's decision to not exclude adverse event reports that bore directly on the alleged injury in no way supports Plaintiffs' position that they are entitled to extensive discovery into completely unrelated adverse events. Similarly, the opinion in *Martinkovic v. Bangash*, 1987 U.S. Dist. LEXIS 11914, at *4 (N.D. Ill.), merely stands for a conclusion not presently in dispute: receiving adverse event reports may be relevant to a defendant's knowledge of those adverse reactions. The opinion nowhere says that the adverse event reports unrelated to plaintiffs' injuries are relevant and subject to discovery. And in Sabel v. Mead Johnson, 737 F. Supp. 135, 140-141 (D. Mass. 1990), the injury alleged was priapism, and the evidence at issue was an FDA letter concerning the risk of priapism. That opinion does not address the discoverability of adverse event data unrelated to a plaintiff's claimed injuries. Finally, Plaintiffs cite Glynn v. Merck Sharp & Dohme (In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.), 2013 U.S. Dist. LEXIS 51552, at *1 (D.N.J.) (Mem. at 18), but that decision does not examine the scope of discover of adverse event data. Glynn merely stands for the proposition that plaintiffs should be allowed discovery into adverse event data related to their alleged injuries—exactly the scope of discovery AbbVie has already agreed to provide.

For all of these reasons, this Court should deny Plaintiffs' request that AbbVie produce the entire AndroGel adverse event database.

B. Producing lower-level source data from the adverse event database would be duplicative and unduly burdensome.

Within the adverse event database, Plaintiffs have asked for two types of information: (1) top-level data about reported adverse events, as entered into the database by people known as "coders"; and (2) lower-level, underlying source material that is described in or linked to the database, including correspondence from reporters of adverse events as well as a variety of regulatory forms (*i.e.*, MedWatch) that AbbVie is required to submit to the FDA in connection with individual adverse event reports. AbbVie has already agreed to produce a portion of the available top-level data for *all* adverse events (even irrelevant ones) and then further offered to provide underlying MedWatch forms for *all relevant* adverse events (after Plaintiffs review the top-level data and the parties agree on which adverse events are relevant). Plaintiffs apparently deem this production insufficient and have refused to narrow their request.

Producing further top-level data and "all" lower-level data would be duplicative because Plaintiffs are already receiving all of the important information from the adverse event reports that AbbVie has agreed to produce. AbbVie has agreed to produce a report for all adverse events with the following information: (a) source of report, (b) country where reported, (c) age of patient, (d) dose of drug, (e) treatment duration until onset of event, (f) outcome of event, (g) description of reaction, and (h) comments. AbbVie will also produce all of the terms or codes (including the verbatim terms) associated with these reports, including hit counts. In other words, the hit reports will allow the Plaintiffs to see and understand exactly how every adverse event was reported and then coded in the database from the most specific terms (the verbatim and lower level terms) to the most broad terms (the preferred and high level terms). And, on top of all

⁶ In recent discussions, the Plaintiffs have requested that AbbVie identify every single available field in the database before agreeing to receiving anything less than "everything." As AbbVie has explained to the Plaintiffs, AEGIS contains a large number of fields, many of which are irrelevant or duplicative of information AbbVie has already agreed to provide. Also, the burden of summarizing and providing data for all adverse event fields is significant and will only delay production of the data for relevant adverse events. AbbVie is willing to meet-and-confer on additional top-level information. But that discussion should occur after Plaintiffs have identified reviewed the top and lower level information provided, so that the parties can have that discussion in the context of particularly relevant adverse event types.

that, AbbVie will produce the lower-level MedWatch forms for the agreed relevant events, which contain the reporter narratives, all key biographical data about the injured patient, and in many instances descriptions of follow-up investigatory and assessment efforts by the company. Plaintiffs will receive this information in searchable, electronic format, with AbbVie removing information only to comply with the protective order and applicable regulations. Thus, all key information that Plaintiffs claim to need for evaluating signals or notice or causation will be produced. The rest of the information in the database is simply irrelevant to Plaintiffs' efforts to establish notice or causation in the manner they have articulated (*i.e.*, to show what AbbVie knew, and when).

Producing lower-level data for *all* adverse events, beyond the MedWatch forms for the agreed-upon relevant events, would be unduly burdensome, because it is duplicative of the top-level data and because it will require AbbVie to redact, from the voluminous medical and other records of individual patients and correspondence about individual patients, patient identifying information that the law protects from disclosure. A laborious, page-by-page redaction review is required at great time and expense. If such a review is determined to be necessary, Plaintiffs should bear the expense of completing it. *McClain v. Hoffman-LaRoche*, Cause No. IP 02-99-C (S/M) ECF No. 344-3, Ex. 2 (S.D. Ind. Jan. 13, 2004) (ordering plaintiffs to pay for production of lower-level data), but they have refused.

Plaintiffs also argue that they need the lower-level data to investigate whether AbbVie "properly categorized" each adverse event—in other words, to make sure that AbbVie did not describe a heart attack as a broken ankle. This justification is speculative and without foundation and not a proper basis for discovery. *See, e.g., Central States, Southeast and Southwest Areas Pension Fund v. Waste Management of Michigan, Inc.*, 674 F.3d 630, 637 (7th Cir. 2012) (mere speculative allegations should not entitle a party to expansive discovery); *Higgason v. Hanks*, 54 F. App'x 448, 450 (7th Cir. 2002) (discovery is not justified if allegations are speculative). There is neither any allegation nor evidence that AbbVie miscoded adverse event data. AbbVie is under a legal duty to accurately code and report adverse events to the FDA and Plaintiffs' counsel

cannot appoint themselves to act as the FDA's inspector. If Plaintiffs' approach were accepted, there would be no end to Plaintiffs' double-checking of AbbVie's records. Furthermore, as described above, AbbVie is already willing to provide top-level data and scientific codes for all adverse events and lower-level MedWatch forms for all relevant adverse events. Further requests for lower-level data are plainly unwarranted.

III. This Court should deny Plaintiffs' motion to compel further responses to interrogatories.

Plaintiffs' motion to compel further interrogatory responses stems directly from their own abuse of that discovery device. They have served hundreds more interrogatories than the rules allow, and many of those interrogatories are so broad and require so much information that there is no realistic way to answer them except, as Rule 33 allows, to refer to specific categories of documents that AbbVie has already produced and is in the process of producing. This Court should deny Plaintiffs' motion.

A. Plaintiffs have vastly exceeded the permissible number of interrogatories.

Plaintiffs have moved to compel further answers to 71 interrogatories (including subparts). That is the first sign that something has gone seriously wrong with the discovery itself. Rule 33(a) sets a ceiling of 25 interrogatories, a limit that may not be exceeded without stipulation or leave of court. Plaintiffs have already served on AbbVie 100 separately numbered interrogatories.

And those separately numbered interrogatories actually contain a far greater number of interrogatories. To avoid allowing subparts to skirt the limit, Rule 33(a) provides that every discrete subpart is counted as a separate interrogatory. Advisory Comm. Notes, 146 F.R.D. 401, 676 (1993). Plaintiffs' interrogatories typically contain many discrete subparts. When the true number is counted according to the Rule, Plaintiffs have already served on AbbVie 522 interrogatories. Even if one accepts Plaintiffs' argument that the Rule's limit of 25 interrogatories is unsuitable for an MDL, serving over 20 times that many is absurd. It can have no effect other than to lead to discovery disputes and unnecessary pleas for the Court's attention.

Here, as an example, is the text of one interrogatory on which Plaintiffs have moved to compel:

INTERROGATORY NO. 8:

Identify the names and state the present and/or last know[n] address(es) of the individual(s)/employee(s) with the most knowledge pertaining to ANDROGEL, including but not limited to:

- (a) The Product manager(s) at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual by time period;
- (b) The sales representative(s) (whether nationally, regionally, etc.) at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual(s) by time period;
 - i. If the sales representative was a regional position, please identify all regions that Defendants utilized and the person(s) most knowledgeable for each specific region, including his/her last known address if he/she is no longer employed with Defendants.
- (c) Describe the sales and marketing organizational structure utilized by YOU regarding ANDROGEL;
- (d) The safety and compliance individuals in charge of reporting adverse reactions and complaints of side effects to the FDA or any other agency, and investigating all adverse reactions and complaints of side effects, at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual(s) by time period;
- (e) The person or persons at all times responsible for Quality Assurance with regard to ANDROGEL;
- (f) Defendants' liaison(s) to the FDA, whether or not part of the regulatory affairs department, with regard to ANDROGEL, at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual(s) by time period;
- (g) Defendants' researcher(s) and developer(s) responsible for ANDROGEL at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual(s) by time period;
- (h) Defendants' scientific researcher(s) of ANDROGEL, at all times Defendants manufactured, produced, promoted, formulated, created,

- designed, sold and/or tested ANDROGEL, identifying the individual(s) by time period;
- (i) Defendants' marketing and/or detailing of ANDROGEL at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual(s) by time period;
- (j) Defendants' Chief Medical Officer, at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual by time period;
- (k) Defendants' Chief Executive Officer ("CEO"), at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual by time period;
- (1) Defendants' President, at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual by time period;
- (m) Defendants' Chief Financial Officer ("CFO"), at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual by time period;
- (n) Defendants' Chief Information Officer ("CIO"), at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual by time period;
- (o) Defendants' regulatory affairs person(s), at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual by time period;
- (p) Defendants' liaison(s) with any outside the United States subsidiary that manufactures, markets, promotes distributes, and/or sells ANDROGEL outside the
- (q) Defendants' General Counsel, and/ or the names of all associate general counsel;
- (r) Defendants' Chief Operating Officer ("COO"), at all times Defendants manufactured, produced, promoted, formulated, created, designed, sold and/or tested ANDROGEL, identifying the individual by time period; and
- (s) Members of any International Product Team maintained or utilized by YOU.

In this single numbered interrogatory, AbbVie is directed to provide information as varied as describing the marketing organizational structure for AndroGel (subpart (c)), identifying every sales rep (subpart (b)), and naming every in-house lawyer (subpart (q)). The interrogatory alone

contains at least 20 discrete subparts⁷—and the subparts are preceded by a warning ("including but not limited to") to indicate that this very long list is not exhaustive!

This interrogatory is in fact even broader than it appears on first reading. First, it covers the time period "April 1999 to the present." (Interrogatories page 6, definition 14.) So when the subparts state that individuals must be identified "by time period," AbbVie is being directed to identify persons most knowledgeable in stages over a 15-year period. Second, the task is made even more difficult because the definition of "Defendants" includes not just AbbVie, but all "predecessor business entities," by which Plaintiffs mean Abbott Laboratories and Solvay, each of which previously sold AndroGel in the United States. AbbVie is being directed to identify individuals who worked during a 15-year period for three different companies. Third, AbbVie is directed not only to provide the individuals' present or last known addresses (as stated at the beginning of the interrogatory) but also their "present or last known place of employment." (Interrogatories, page 4, definition 6.)

At this point it bears repeating: this is only one of the 100 separately numbered interrogatories that Plaintiffs have already served on AbbVie. And interrogatory number 8 is not even the worst offender. Plaintiffs themselves broke interrogatory number 10, for example, into 26 discrete subparts. All told, Plaintiffs' interrogatories span 58 pages.

The Federal Rules establish specific limits on discovery, to avoid allowing it to impose unreasonable burdens by sprawling out of control, but Plaintiffs have simply ignored those limits and attempted to bury AbbVie under a mountain of interrogatories. This is, of course, the exact same approach that Plaintiffs recently took to depositions, insisting to the Court that there could be no limit on the number of depositions. This Court rejected that approach. At the January 13

⁷ *Imbody v. C&R Plating*, 2010 WL 567317, at *1 (N.D. Ind.) ("Once a subpart of an interrogatory introduces a line of inquiry that is separate and distinct from the inquiry made by the portion of the interrogatory that precedes it, the subpart must be considered a separate interrogatory no matter how it is designated."). As courts have explained, "if the first question can be answered fully and completely without answering the second question, then the second question is not 'factually subsumed within and necessarily related to the primary question." *Thermal Design v. Guardian Bldg.*, 2011 WL 1527025, at *2 (E.D. Wis.).

case management conference, this Court set them straight and stated, in unambiguous terms, that there would be a limit to the number of depositions.

This Court should rule the same way with respect to the number of interrogatories. In other pharmaceutical product liability MDLs, plaintiffs are commonly limited to 50 interrogatories, with each discrete subpart counted separately. *See, e.g.*, Ex. 3, Bextra Pretrial Order No. 4 ¶ 20; Ex. 4, Chantix Pretrial Order No. 4 at 3; Ex. 5, Zoloft Joint Pretrial Order No. 13 at 5. The same limit should be imposed here, and Plaintiffs should be required to state which of their interrogatories, with each discrete subpart counted separately, are the 50 to which they are seeking answers.

B. Plaintiffs' interrogatories are so broad and non-specific that they are all but impossible to answer.

To the abuse of serving far too many interrogatories, Plaintiffs have added the abuse of making the interrogatories so broad and non-specific that answering them is a staggeringly burdensome task, if it is possible at all. Here again a few examples (all of interrogatories on which Plaintiffs have moved to compel) suffice to illustrate the problem.

Interrogatory 19 directs AbbVie to identify (again, meaning to provide the name, current or last known address, and current or last known employer) every single employee, over a 15-year period at AbbVie, Abbott Laboratories, and Solvay, who has any "knowledge of any and all studies or testing" of AndroGel. How could AbbVie possibly determine today which employees, at Solvay 10 years ago, had any knowledge of AndroGel testing? And what is the point of assembling an incredibly long list of every employee who ever knew anything about testing?

Interrogatory 38 directs AbbVie to identify over the same 15-year period every "consultant, advisor, organization, researcher, doctor, nurse, public health advocate government body, or any other person" who made "any examination, inquiry, study, investigation, or evaluation concerning AndroGel." AbbVie has no way of identifying everyone in the world who has examined AndroGel, inquired about it, evaluated it, etc. And the Court will note that this interrogatory is not in any way limited to any subject relevant to this case.

Interrogatory 93 directs AbbVie to provide the "complete names and addresses of all persons and/or entities involved in any way with the design, development, manufacture, marketing, testing, investigation, evaluation, distribution, packaging, promotion, labeling, and/or sale of ANDROGEL." Of course the usual 15-year period applies. It is impossible to calculate exactly how many names this interrogatory requests, but it is surely hundreds and hundreds. And once again, the interrogatory contains no limitation on its subject to make it relevant to this case.

To address this problem, AbbVie has repeatedly asked Plaintiffs to identify what information they actually need—*i.e.*, to narrow the interrogatories. Plaintiffs have refused to do so, instead insisting that AbbVie say what information it is willing to provide. Forcing AbbVie to guess at Plaintiffs' discovery is a fruitless exercise and does nothing to advance the case. Plaintiffs should be required to draft narrower interrogatories that seek relevant information and are actually capable of being answered.

C. AbbVie's responses comply with Rule 33(d).

Given the extraordinary number of Plaintiffs' interrogatories and their extraordinary breadth, AbbVie had no choice but to respond to many of them by referring Plaintiffs to the information contained in business records that AbbVie has produced and is in the process of producing. That is the approach that Rule 33(d) specifically authorizes. *Nan Wei v. Deere*, 2013 WL 1689053, at *3 n.2 (C.D. Ill.) ("Defendant is entitled to respond to interrogatories by specifying business records (such as personnel files) in which the answers can be found."); *Allen v. Chicago*, 2010 WL 118372, at *2 (N.D. Ill.) (same).

AbbVie's interrogatory answers referred Plaintiffs to categories of responsive documents, and AbbVie will supplement those references as more documents are produced and as more information becomes known. For example, for the interrogatories (6, 10, 16, 20, 23-32, 38, and 81) asking about "clinical trials," "foreign regulatory information," and "development and

⁸ In the spirit of compromise, AbbVie has offered to answer 14 of the interrogatories (Nos. 8, 10, 15, 20, 38, 40, 48, 52, 55, 60, 61, 65, 99, and 100) within 90 days. Plaintiffs have not agreed to stand down from any of their requests at this point.

design," AbbVie has directed Plaintiffs to the already completed production of the IND/NDA files for AndroGel. For the interrogatories (8, 19, and 44) related to "knowledgeable employees," AbbVie referred to its initial disclosures and stated that "the names of additional individuals will appear in the documents to be produced including but not limited to organizational charts for the following: Regulatory Affairs, Research & Development, Global Medical Affairs, Health Economics & Outcomes Research, Pharmacovigilance and Patient Safety, and Commercial." All of those organizational charts have already been produced, and Plaintiffs have already deposed a Rule 30(b)(6) witness on those issues.

The effort needed to compile the information Plaintiffs have requested—such as the identity of every employee who in the past 15 years has ever known anything about AndroGel testing (interrogatory 19), and the names of every person in the past 15 years involved with AndroGel's design, development, manufacture, marketing, testing, investigation, evaluation, distribution, packaging, promotion, labeling, and/or sale (interrogatory 93)—is the same for Plaintiffs as for AbbVie. In other words, "the burden of deriving or ascertaining the answer will be substantially the same for either party." Rule 33(d). In that circumstance, the rule requires "nothing beyond offering records for inspection in the same direct and economical manner as they would be to the party from whom they are sought." *Johnson v. Kankakee*, 2007 WL 1431874, at *2 (C.D. Ill.). Given that AbbVie "would have to sift through [its] files, which would be just as easy for [Plaintiffs] to do" AbbVie need not do Plaintiffs' work for them. *Id.*; *see also C.A. v. AMLI at Riverbend*, 2009 WL 1605807, at *2 (S.D. Ind.) ("There is, accordingly, no basis on which the Court should or could order them to do more.").

What's more, AbbVie is producing its records in a manner that makes them especially useful for Plaintiffs to locate the information they want. Under the heavily negotiated ESI protocol, ordered by the Court, Plaintiffs receive image load files for every document, which can be searched, and Plaintiffs also receive metadata that includes the author name, a variety of dates, the file path, and any custodian names. It will be no more difficult for Plaintiffs than for

AbbVie to review the documents to which AbbVie has referred, based on how documents are being produced and using search functions and review capabilities.

Plaintiffs have two complaints about AbbVie's references to business records. One is that not all of the business records have yet been produced. That is true, but it indicates only that Plaintiffs' interrogatories are premature. AbbVie has been speedily producing documents on the schedule ordered by the Court.

Second, Plaintiffs complain that AbbVie has not identified documents by the Bates numbers stamped on them at the time they are produced. Yet the Rule does not require Bates numbers. It only requires a response "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." Rule 33(d)(1). Plaintiffs' insistence that AbbVie must identify *particular pages*, within the millions of pages of documents that Plaintiffs have demanded AbbVie produce, is a burden that the Rule does not impose. As the Seventh Circuit has held, "*Rule 33(d) does not require documents to be identified by Bates-stamp*, only that the documents be clearly identified." *Continental Ins. v. Chase Manhattan Mortgage*, 59 F. App'x 830, 838-39 (7th Cir. 2003) (emphasis added).

D. Plaintiffs' arguments about AbbVie's responses are meritless.

The last six pages of the motion to compel raise various objections to AbbVie's responses to certain interrogatories. Those objections have no merit. The interrogatories at issue are too broad and seek information found in documents that have already been produced or that will be produced.

1. Interrogatories 10, 20, 23-32, 38, 81

These interrogatories "seek information regarding clinical trial, studies, and scientific literature related to AndroGel and TRT." (Mem. at 22.) For the reasons given above, most of these requests are grossly overbroad, ⁹ and Plaintiffs have refused to narrow them. But in attempt

⁹ For example, interrogatory 81 and its 13 discrete subparts direct AbbVie to "[i]dentify all clinical trials or other studies that were ever conducted by or on behalf of Defendants concerning

to compromise, AbbVie has already agreed to supplement its responses to interrogatories 10, 20 and 38. 10

In addition, AbbVie has already produced many documents on these categories as part of its production of IND/NDA files. The responsive information can be found through searches of those files. AbbVie will also be producing numerous other documents on these topics.

2. **Interrogatory Nos. 8, 19, 44**

Plaintiffs claim that AbbVie has "refuse[d] to "identify potential witnesses with knowledge," that these interrogatories seek. (Mem. at 23.) That is wrong. AbbVie's initial disclosures identified five people most knowledgeable as well as eight additional potential custodians. Plaintiffs thus received the substance of the information they seek. In addition, AbbVie has produced a wide variety of corporate organization charts, and, on December 18, 2014, Plaintiffs took a Rule 30(b)(6) deposition about AbbVie's corporate organization.

In an attempt to compromise, AbbVie has offered to provide a supplemental response to interrogatory 8. But, for the reasons stated above, interrogatories 19 (all present and past employees with any knowledge of any testing) and 44 (every person who has received, evaluated, investigated, or responded to any complaint about AndroGel) remain hopelessly overbroad and unduly burdensome.

3. Interrogatory Nos. 39-42, 43, 68-74

These interrogatories ask AbbVie to identify every adverse reaction ever reported regarding AndroGel. For example, No. 40 asks AbbVie to "[i]dentify all reports of adverse reactions, injuries, and/or adverse events in humans that YOU ever became aware from any

any product (whether or not ever approved for marketing or submitted to any Regulatory Authority for such approval) ever containing testosterone as one of its components (whether such trial or study was completed or not)." This interrogatory is not even limited to AndroGel or any other medication taken by any plaintiff.

¹⁰ AbbVie has also agreed supplement its responses to 14 additional interrogatories, and has agreed to meet and confer about supplementing a limited set of others. But Plaintiffs have insisted that AbbVie must provide "a complete schedule for substantive responses to the remainder to be completed within 90 days."

source." AbbVie has no way to provide this information in narrative form; it will be found in documents, including the IND/NDA production, which is already complete.

4. Interrogatory Nos. 11-14, 18, 37, 64, 77

These interrogatories seek "information regarding AbbVie's FDA submissions for AndroGel" and AbbVie's "label and warning information." (Mem. at 24.) Again, AbbVie has already produced the vast majority of this information in its NDA/IND production. In addition, AbbVie referred to other records. For example, in response to interrogatory 18, AbbVie pointed Plaintiffs to letters dated April 28 and September 19, 2014, which were sent to health care providers. Additional responsive information will also be provided in AbbVie's future document productions.

5. Interrogatory No. 16

Interrogatory 16 asks for all information regarding "any government agency in any country worldwide that declined to approve or challenged, or asked for additional study before approving YOUR application to market ANDROGEL." Despite its overbreadth in a case about AndroGel in the United States, AbbVie has already provided responsive information through its IND/NDA production. AbbVie has also offered to produce certain foreign regulatory information, but Plaintiffs rejected AbbVie's request, and negotiations continue.

6. Interrogatory Nos. 46, 48, 49, 52, 84-87, 96, 97, 100

These interrogatories seek information regarding "marketing, advertising and promotion of AndroGel and the individuals responsible for these activities." (Mem. at 26.) AbbVie has already provided much of the responsive information in initial disclosures, organizational charts, and the Rule 30(b)(6) deposition on corporate organization. Plaintiffs will also receive additional responsive information as the document production progress.

7. Interrogatory No. 92

Interrogatory 92 asks AbbVie to "[i]dentify all persons and/or entities paid by the Defendants for consulting services of any kind concerning AndroGel." This interrogatory is

plainly too broad. It is not limited to Plaintiffs and their alleged injuries or to any other matter relevant to the case.

8. Interrogatory No. 6

This interrogatory seeks "design used by YOU" for AndroGel and any changes to it. (Mem Ex. 4 at No. 6.) It is far too broad because it asks AbbVie to identify every change it has made to AndroGel over all time regardless of whether the change has any relevance to Plaintiffs' alleged injuries. Further, this information is can be found in publicly available patent documents and AbbVie has already provided information responsive to this interrogatory in the NDA/IND production. For example, the NDA/IND production provides information regarding the composition and manufacturing of AndroGel. (*See, e.g.*, ABBVIE-FST25-137.)

9. Interrogatory No. 7

This interrogatory and its 5 subparts asks AbbVie to "[i]dentify any and all insurance agreements under which any person carrying an insurance business may be liable to satisfy part or all of a judgment" in this case. (Mem. Ex. 4 at No. 7.) AbbVie has already provided the substance of the requested information in its initial disclosures, which state:

AbbVie is self-insured for purposes of the AndroGel product liability litigation. There is a \$2,000,000 self-insured retention followed by a \$10,000,000 insurance policy with the ACE American Insurance Company that is known in the insurance industry as a "fronted" insurance policy. The fronted insurance policy is issued on AbbVie's behalf by a licensed, admitted insurer but does not transfer the risk to the insurance company. It allows self-insurers to comply with financial responsibility laws imposed by many states that require evidence of coverage written by an admitted insurer.

At this time, Abbott is not aware of any insurance carrier that may be called upon to provide coverage to it for this matter.

For all of the reasons stated above, Plaintiffs' motion to compel AbbVie's interrogatory answers should be denied.

CONCLUSION

For the foregoing reasons, AbbVie respectfully urges this Court to deny Plaintiffs' motion to compel and enter an order with the following provisions.

On the subject of *King v. Solvay*:

- (1) allow AbbVie 120 days to review and redact its *King* production and produce the relevant and responsive documents to Plaintiffs;
- (2) after Plaintiffs have reviewed the *King* documents, give the parties an opportunity to confer about any additional archival discovery that Plaintiffs are requesting from the Solvay era; *and*
- (3) defer ruling on Plaintiffs' request for *King* deposition transcripts until the deposition protocol has been approved, and, in the event any transcripts must be produced, allow AbbVie time to review and redact them and produce the relevant and responsive transcripts to Plaintiffs.

On the subject of the adverse event database:

- (1) allow AbbVie to proceed with its planned production of certain top-level data for all AndroGel entries; *and*
- (2) deny Plaintiffs' request to compel AbbVie to produce lower-level source material other than MedWatch forms for all relevant adverse events that are agreed upon by the parties after Plaintiffs review the top-level data.

On the subject of interrogatories:

- (1) deny Plaintiffs' motion to compel; and
- (2) order Plaintiffs to identify no more than 50 narrow interrogatories, with each discrete subpart counting as a separate interrogatory, on which they are seeking answers from AbbVie.

Dated: February 6, 2015 Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Marissa S. Ronk, hereby certify that on February 6, 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/ Marissa S. Ronk